



You can also call Boston Scientific customer service at 1.888.272/100/14o/requestroopies of the Directions for Use (DFU).

For more-information about indications, contraindications, warmings and instructions for the Express of Linguistic mounted Stent System, visit www.bostonseientific.com

CAUTION: Federal (USA) law restricts these products to sale by or on the order of a doctor.

Delivering what's next."

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#### of 16

## Treating iliac artery disease

Your doctor wants you to have a stent placed in your iliac artery. This is to help treat your iliac artery disease. This guide explains the procedure and what you can expect from start to finish. A glossary at the end of this guide defines common medical terms about this procedure.

You will also learn steps you can take to live a healthier life with liac artery disease.

# Iliac artery disease treatment options

and the second s

liac artery disease is caused by the narrowing deposits called plaque. Over time, this plaque usually caused by a buildup of fat or calcium narrowing can also be called stenosis. It is: can build to a total blockage of the artery. of the arteries leading to the legs. This This is also called atherosclerosis.

What is iliac artery disease?

Healthy Arteny

Varrowed

When a leg doesn't receive enough blood flow because of a blockage in an artery, it can cause pain in the lower leg when walking. In severe cases, low blood flow can cause tissue loss.

#### lliac Arteries



at the base of the aorta, just behind the navel

(belly button). The iliac arteries branch into

smaller arteries that supply blood to the

legs and feet.

You have two iliac arteries, one located at the top of each leg. The iliac arteries start

There are four different treatment options for iliac artery disease. All four treatment options focus on increasing blood flow to the legs. The type of treatment your doctor recommends depends on your symptoms.

### 1. Medical therapy

may prescribe drugs to decrease clotting, expand the arteries; lower blood pressure, and reduce For patients with mild to medium symptoms, doctors often choose medical therapy. This can include drugs, exercise, and regular checkups. Doctors also say to stop smoking. The doctor cholesterol. Regular checkups can help determine if more treatment is needed.

#### 2. Angioplasty

angioplasty is done. Angioplasty is less invasive than surgery, and the patient remains awake while is inserted into the artery. A small balloon located on the tip of a catheter is moved to the site of the narrowing and inflated to reduce the blockage. The balloon is deflated and removed after the A procedure, angioplasty, can also treat vessel narrowing. A thin tube known as a guide catheter the doctor performs the procedure.

### 3. Iliac artery stenting

During this procedure, a small balloon is inflated in the artery. The balloon has a small mesh tube called a stent wrapped around it. It expands the stent in the artery which keeps the artery open and helps prevent further narrowing.

week. In an iliac artery bypass, a healthy vein is removed from another part of your body. This vein There are two types of surgery to treat iliac artery disease, During an iliac artery endarterectomy, the doctor makes an incision in the pelvis. This exposes the iliac artery and the plaque inside the For patients with severe narrowing with blocked blood flow to the legs, surgery may be needed. artery is removed. Patients who have this type of surgery are usually in the hospital for about a is used to make a new path around the narrowed or blocked iliac artery. Patients are also in the hospital for about a week after this surgery.

# You should not have a stent placed in your iliac artery if you have any of the following conditions:

- You are unable to take medicines that make your blood take longer to clot (anticoagulants).
- You are unable to take medicines that make your blood cells slippery and make it more difficult for your blood to clot (antiplatelets).
- You are allergic to stainless steet, chromium or nickel. These are the metals. used to make the Express® LD lliac Premounted Stent System.
- You have poor kidney function.

Note: It is very common for your doctor to prescribe specific medications before, during and after your stent placement. Common drugs that may be prescribed by your doctor include anticoagulants and antiplatelets. These medications are intended to help decrease the risk of forming a blood clot in your arteny. Please check with your doctor to find the right medication for you.

The placement of stents in blood vessels is done to treat blockages and to try to prevent re-narrowing.

As with any stent procedure, there is chance that complications may occur, - 13 including, but not limited to, the following:

- Air bubble(s) in your artery
- Allergic reactions
- (The Bleeding Blood clot(s)
- · Bruising at you groin area
- - Heart attack ■ Death

- Injury or damage to your artery or wall of the artery. This could require emergency surgery
  - Leakage of blood where the catheter was inserted
- Movement of the stent from where it was original placed
- Restenosis or re-narrowing of the artery around or within the stent

In the event of complications, surgical removal of the stent may be required

Your doctor and the medical staff will monitor you during and after the procedure require treatment. He or she will determine what type of treatment you need. for complications. If a complication does occur, your doctor will decide if you

# Summary of clinical data

The benefits of undergoing iliac stent placement can be improved blood flow to the legs through the artery being treated. If you had symptoms before surgery, they might improve or go away.

Benefits

The safety and effectiveness of the Express LD Premounted Stent System was compared to the Palmaz® Stent in the International MELDDIE-study. It included 151 patients. The study results showed that patients who received an Express LD. Stent had similar blood vessel narrowing at six months compared to patients who received a Palmaz Stent. The occurrence of major adverse events was 6.3% at 6 months and 10.2% at 2 years for the Express ILD Premounted Stent System. Major adverse events include death, repeat angioplasty and distal embolization.

The long term outcome (beyond 24 months) for this permanent iniplant is unknown.

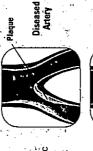
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# Below is a typical checklist. Your doctor may ask you to go through this before your procedure.

- Tell your doctor about any medications you are taking.
- Take all your medications with you.
- Let your doctor know about any allergies you have. It is important he or she knows about allergies to contrast dye, iodine, cobalt, chromium,
  - nickel, titanium, stainless steel or plastics.
- Tell your doctor if you cannot take aspirin or blood thinning medicines:
   These medications are usually prescribed before and after your procedure.
- Do not eat or drink anything after midnight on the night before your procedure.
- ☐ Follow the instructions you receive from your doctor and nurses.
- Make sure you understand the possible risks and benefits of your iliac stent procedure.
- You could be given a sedative to relax you before starting your stent procedure. The sedative can make you sleepy.

- 1. A small puncture is made in your groin. A needle is used to gain access to the femoral artery. This wire is then fed through the femoral artery and moved up, into the illac artery. A catheter is then put in your body. The doctor moves it to the narrowed section of your lilac artery. All wire and catheter movement is done using x-rays for a guide. The diseased artery first needs to be enlarged to make room for the stent. To do this, the doctor.

  2. The diseased artery first needs to be enlarged to make room for the stent. To do this, the doctor.
  - places a small, deflated balloon over the wire and through the catheter to the blocked area of the illac arrery. When the balloon is in the correct position, it is inflated. This pushes the plaque buildup aside and reopens the artery to restore blood flow.
    - The balloon is deflated and removed, and a small, metal mesh tube called a stent is advanced into the same blocked area of the artery and expanded against the artery wall.
- 4. After the stent is implanted, the catheter and wire, are removed and the puncture site in your groin is closed. The stent remains in place and is designed to help keep the artery open and prevent future narrowing of the iliac artery.







Images courtery of Boston Scientific. Images are for illustration purposes only, and are not necessarily to scale. 11 of 16

# After a typical iliac stenting procedure

- You may feel sleepy from the sedative given to you. This will wear off over the next few hours.
- You will be taken to a unit where nurses and doctors can monitor you.
- Your heart rate, blood pressure, brain function and the entry site in your groin will be checked frequently.
- You will be asked to drink a lot of liquids to flush the contrast dye out of your system.
   You will have to stay in bed for several hours.
   You will be asked to keep your leg straight so the entry site in your groin can heal well.
- You may need a short hospital stay.

- You should alert your doctor or nurse if you experience any of these symptoms.
- Severe dizziness, near blackout or fainting
   Severe headache that doesn't go away
   Sudden blurriness or blindness in one
   And also
  - or both eyes

    Sudden weakness or clumsiness in
- your hand o Sudden weakness or paralysis of the
  - o Sudden weakness of paralysis of face, arm or leg of Speech or o Unexplained slurring of speech or
- difficulty understanding what is said or Pain, bleeding or infection at the entry site in your groin
- You should avoid straining yourself or lifting items heavier than 5 pounds until your doctor lets you know that it is okay to do so.

You's tent implant card shown at right tells: doctors, dentists and nurses that you have a stent pimplanted in your illac artery. This card also has: ...

Your stent implant card

- The doctor who put in your stent,
  - The doctor's phone number
- The date the stent was put in
   Where the stent was placed in your liac artery
- The size of the stent
- . The manufacturer's lot number for the stent

The card gives your doctors, dentists and nurses information that is needed if you have any special diagnostic tests such as:

MΒ

There are also phone numbers on the card that your doctors can call if they have any questions. You discharge nurse will fill in the card, if he or she does not, please call the doctor who placed the stent for this information.

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# Living with iliac artery disease

You cannot control some risk factors. You cannot change your age, gender, ethnic Treatment for iliac artery disease includes controlling things that cause the disease. background or family history. However, you can change many of the risk factors for this disease.

# Your doctor may suggest the following healthy lifestyle changes:

- Lose excess weight
- Quit smoking
- Exercise regularly
- Control stress and anger
- Decrease fat in your diet

Limit alcohol consumption

success of iliac artery disease treatment. Talk to your doctor today about how Reducing your risk factors can also have a positive impact on the long-term to increase your chances for a healthier outcome and a more rewarding life with iliac artery disease.

#### Glossary

A minimally invasive treatment of the arteries that opens blocked arteries.

### Medicines that slow down the clotting of blood. Anticoagulant and Antiplatelet

A blood vessel that carries oxygen-rich blood Artery

away from the heart to the rest of the body.

### Atherosclerosis

A disease in which the flow of blood is slowed down by plaque in the arteries.

### Balloon Angiopfasty

Inflating a balloon catheter in the blood vessel to open a blocked artery.

### Balloon Catheter

A thin tube with a balloon attached to the tip that can be inflated to open blocked arteries.

#### **Blood Vessel**

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Any of the veins and arteries that carry blood to and from the heart.

A long, flexible tube that can be passed through the blood vessels.

#### Contrast

X-ray dye used in diagnostic tests.

#### Claudication

Pain that develops in the calf muscles of the legs. It can cause limping and an inability to walk long distances.

### Femoral Artery

The blood vessels that supply blood to the legs.

#### Iliac Arteries

The blood vessels that supply blood to the legs.

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### Glossary continued

alternate route for blood to flow to the legs around narrowed or blocked iliac arteries. **lliac Artery Bypass** A surgical procedure used to create an

### lliac Artery Endarterectomy

A surgical procedure that removes plaque from the walls of the Iliac arteries.

## Minimally Invasive Procedure

A procedure that uses small instruments or site and cause a smaller amount of trauma devices to reduce the size of the insertion

MRI (Magnetic Resonance Imaging)
A method of using a magnetic field and radio waves to produce detailed images of the inside of the human body.

#### Occlusion

Blockage of blood flow in the artery.

Peripheral Related to areas of the body outside the heart and brain.

#### Plaque

A buildup of cholesterol, fat calcium and coflagen in a vessel.

#### Restenosis

Re-narrowing of the artery after treatment.

#### Sedative

relaxed and sleepy. Also called sedation. A type of medication that makes you

#### Stenosis

A narrowing of the artery.

An expandable metal tube that supports the blood vessel wall and maintains blood flow through the opened vessel.

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Stent Identification Information

[score]

PLEASE CARRY YOUR CARD AT ALL TIMES

Product Lot Number

Product Lot Number

Stant Location

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Scientific

OVER - THE - WIRE Premounted Stent System Express® LD Iliac

#### ₽ ONLY

physician. Caution: Federal Law (USA) restricts this device to sale by or on the order of a

Please read instructions carefully prior to use

#### WARNING:

with hospital, administrative and/or local government policy. resterilization may also create a risk of contamination of the device and/or cause patient single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or barrier is damaged. If damage is found, call your Boston Scientific representative. For Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile illness or death of the patient. After use, dispose of product and packaging in accordance disease(s) from one patient to another. Contamination of the device may lead to injury, infection or cross-infection, including, but not limited to, the transmission of infectious failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device

#### DEVICE NAME:

Express LD Iliac Premounted Stent System

### DEVICE DESCRIPTION:

diameter. The premounted stent system balloon catheter is also offered in two shaft post stent dilatation. The premounted stent system is available in a variety of stent lengths inflation pressure of 12 atm (1216 kPa) that can be used for initial stent placement and markers embedded in the shaft to aid in the placement of the stent. The SDS is compatible with .035 in. (0.89 mm) guidewires. The SDS balloon has a maximum steel balloon expandable stent. The stent is premounted on a Stent Delivery System lengths. Table 1 summarizes individual product descriptions and nominal specifications with premounted stent system balloons that expand them from 6 mm to 10 mm in (SDS) equipped with a non compliant balloon. The SDS has two radiopaque balloon The Express LD Iliac Premounted Stent System consists of: 316L surgical grade stainless

larger diameter balloon Note: The diameter of the stent may be increased post-placement by expanding with a

;

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# INTENDED USE/INDICATIONS FOR USE:

diameter of 6 mm to 10 mm. atherosclerotic lesions found in iliac arteries up to 100 mm in length, with a reference The Express LD Iliac Premounted Stent System is indicated for the treatment of

### CONTRAINDICATIONS

Express LD Iliac Premounted Stent System include: contraindications for stent placement. Contraindications associated with the use of the Generally, contraindications for Percutaneous Transluminal Angioplasty (PTA) are also

- Patients who exhibit persistent acute intraluminal thrombus at the treatment site,
- following thrombolytic therapy
- Patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy
- Persons with known allergies to stainless steel or its components (for example nickel)
- Patients who experience the complication of arterial perforation or a fusiform or A lesion that is within or adjacent to the proximal or distal segments of an aneurysm
- sacciform aneurysm during the procedure, precluding possible stent implantation.
- Patients with excessive vessel tortuosity
- Patients with perforated vessels evidenced by extravasation of contrast media

#### WARNINGS:

potential for balloon rupture and possible vessel damage Do not exceed the maximum rated burst pressure. Exceeding this pressure increases the

the site of the implant down the arterial lumen. into the retroperitoneum. The stent may cause thrombus or distal emboli to migrate from stent, may lead to thrombosis, pseudoaneurysm or rupture into a neighboring organ or As with any type of intravascular implant, infection, secondary to contamination of the

ostium into the aorta as this may result in thrombus formation Care should be taken during stent deployment to avoid stent placement beyond the iliac

Do not exceed the maximum expanded stent diameter as per Table 1.

approximate the diameter of the vessel just distal to the stenosis. Overstretching of the artery may result in rupture and life threatening bleeding. To reduce the potential for vessel damage, the inflated diameter of the balloon should

volume of contrast medium and normal saline). Never use air or any gaseous medium in Use only diluted contrast medium for balloon inflation (typically a 50/50 mixture by

Persons with allergic reactions to stainless steel or its components (for example nickel) may suffer an allergic response.

Do not expose the premounted stent system to organic solvents (i.e. alcohol).

This product contains no detectable latex.

The long-term outcome (beyond twenty four months) for this permanent implant is unknown at present.

Stent placement should only be performed at hospitals where emergency peripheral artery bypass graft can be readily performed.

#### PRECAUTIONS:

The device is intended for use by physicians who have been trained in interventional techniques such as percutaneous transluminal angioplasty (PTA) and placement of intravascular stents.

The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect, it should not be used.

Caution should be taken with patients with poor renal function who, in the physician's opinion, may be at risk for a contrast medium reaction.

Prep premounted stent system per instructions given in Operational Instructions. Significant amounts of air in the balloon may cause difficulty in deploying the stent and deflation of the balloon.

Do not attempt to pull a stent where deployment has been initiated back through a sheath or guide catheter, since dislodgment of the stent may result. If a stent that has not been fully deployed needs to be removed, the sheath or guide catheter and the premounted stent system should be removed as a unit.

The SDS is not designed for use with power injection systems. Inflation at a high rate can cause damage to the balloon. Use of a pressure monitoring device is recommended to prevent over pressurization.

Do not attempt to manually remove or adjust the stent on the SDS balloon.

The minimally acceptable sheath and guide catheter French size is printed on the package label. Do not attempt to pass the premounted stent system catheter through a smaller size sheath or guide catheter than indicated on the label.

When a premounted stent system or SDS balloon is in the body, it should be manipulated only under fluoroscopy. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum.

Never advance the premounted stent system without the guidewire extending from the tip.

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Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the stent. If the target lesion is not fully covered, use an additional stent as necessary to adequately treat the lesion.

It is recommended that when stenting multiple lesions, the distal lesions should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent when placing the distal stent and reduces the chances for disrupting the proximal stent.

Prior to stent expansion, utilize fluoroscopy to verify the stent has not been damaged or dislodged during positioning. Expansion of the stent should not be undertaken if the stent is not appropriately positioned in the vessel. If the position of the stent is not optimal, it should not be expanded.

To assure full expansion, inflate the premounted stent system to at least the opening pressure as shown on the labeling and in Table 1. To assure nominal sizing of the stent, inflate the premounted stent system to nominal pressure as shown on the labeling and in Table 1.

Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures, or could result in thrombosis of the side branch.

More than one stent per lesion should only be used when clinically indicated for suboptimal results that compromise vessel integrity and threaten vessel closure, such as edge dissection <a href="https://example.com/ballout">https://example.com/ballout</a>. The second implanted stent should also be an Express® LD Iliac Stent, or a stent of similar material composition, for component compatibility.

Do not attempt to reposition a partially deployed stent. Attempted repositioning may result in severe vessel damage. Incomplete deployment of the stent (i.e. stent not fully opened) may cause complications resulting in patient injury.

Recrossing a previously deployed stent with adjunct devices must be performed with extreme caution to ensure that the adjunct device does not get caught within previously placed stent struts.

In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.

In the event of complications such as infections, pseudoaneurysm, or fistulization, surgical removal of the stent may be required.

Use prior to the "Use By" date.

Table 1. Express® LD ILIAC Premounted Stent System Specifications

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Sheath size [Fr (I.O. in.)]	Stent Diameter (mm)	Pressure [atm (kPa)]	Pressure (atm (kPa))	Usable Length (cm)	Length (mm)	Dia. (mm)	Stent Length (mm)	Product Code
Minimum	Fynandad	Kated	Mominal	Catheler		ĺ	Crimon	

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# MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

conditions is MR Conditional. It can be scanned safely, immediately after placement of this implant, under the following conditions: Non-clinical testing has demonstrated the Express LD stent in single and overlapped

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Spatial gradient field of 700 Gauss/cm or less
- Normal operating mode of the MR system and use of whole body transmit coils only.
- Maximum whole-body-averaged specific absorption rate (WBA-SAR) of
- umbilicus (patient navel). 2 Watts/kilogram, (W/kg), for 15 minutes of scanning for patient landmarks above the

Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below

migration or heating. at field strengths other than 1.5 Tesla or 3 Tesla has not been performed to evaluate stent The Express LD stent should not migrate in this MRI environment. Non-clinical testing

## 3.0 Tesla Temperature Information

based on these non-clinical tests and computer simulation of the patient exposure to the material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was syngo MR A30. The testing was according to ASTM F2182 and the stents were in a electromagnetic fields in MRI yielded the following maximal in vivo rises: temperature rise. Fractured stents exhibited similar heating. Predicted in-vivo heating scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower (RF) heating. RF power was applied for 15 minutes and the conductivity of the phantom Magnetorn Trio, Siemens Medical Solutions MR system, software version Numaris/4, Non-clinical testing of RF-induced heating was performed at 128 MHz in a 3.0 Tesla 1.8 W/kg. The maximal in-vitro temperature rise was 4.0°C when the local SAR was ocation and orientation in the phantom that produced the worst case Radio Frequency

- For landmarks above the umbilious the calculated temperature rise was 5.2°C with an of 2.0 W/kg and a continuous scan time of 15 minutes. uncertainty upper bound temperature of 6.6°C for a whole body average SAR value
- of 1.0 W/kg and a continuous scan time of 15 minutes. uncertainty upper bound temperature of 5.2°C for a whole body average SAR value For landmarks below the umbilious the calculated temperature rise was 4.1°C with an

perfusion in the tissue outside the stent. include the cooling effects due to blood flow in the lumen of the stent and blood The actual in vivo rise is expected to be less than these values as the calculations did not

# 1.5 Tesla Temperature Information

scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower heating. RF power was applied for 15 minutes and the conductivity of the phantom 2.1 W/kg. The maximal in-vitro temperature rise was 2.2°C when the local SAR was material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was stents were in a location and orientation in the phantom that produced the worst case RF body coil MR scanner. The testing was performed according to ASTM F2182 and the Intera Philips Medical Systems, software version Release 10.6.2.0, 2006-03-10 whole Non-clinical testing of RF-induced heating was performed at 64 MHz in a 1.5 Tesla

electromagnetic fields in MRI yielded to the following maximal in vivo rises: based on these non-clinical tests and computer simulation of the patient exposure to the temperature rise. Fractured stents exhibited similar heating. Predicted in-vivo heating

- For landmarks above the umbilious, the calculated temperature rise was 3.2°C with an of 2.0 W/kg and a continuous scan time of 15 minutes. uncertainty upper bound temperature of 4.1°C for a whole body average SAR value
- For landmarks below the umbilious the calculated temperature rise was 3.2°C with an of 1.0 W/kg and a continuous scan time of 15 minutes. uncertainty upper bound temperature of 4.1°C for a whole body average SAR value

perfusion in the tissue outside the stent. include the cooling effects due to blood flood in the lumen of the stent and blood The actual in vivo rise is expected to be less than these values as the calculations did not

### lmage Artifact Information

each end of the length with both sequences partially shielding the lumen in a 3.0 Tesla image artifact extends 13 mm beyond the perimeter of the diameter and 12 mm beyond nonclinical testing using a Spin Echo sequence. With a Gradient Echo sequence the The image artifact extends approximately 7 mm from the perimeter of the device diameter and 6 mm beyond cach end of the length of the stent when scanned in 2007-09-28 MR system with a transmit/receive head coil Intera (Achieva Upgrade), Philips Medical Solutions, software version Release 2.5.3.0

scanned safely with the Medic Alert Foundation (www.medicalert.org) or an equivalent It is recommended that patients register the conditions under which the implant can be

### ADVERSE EVENTS:

device, but are not limited to, the following: Potential adverse events (In alphabetical order) that may be associated with the use of this

- Abscess Aneurysm
- Arrhythmias
- AV fistula
- Bleeding / Hemorrhage
- Death
- Drug reaction or altergic reaction (including to antiplatelet agent, contrast medium, stent materials, or other)
- Embolization of device, air, plaque, thrombus, tissue, or other
- Emergency surgery to correct vascular complications
- Extremity ischemia/amputation
- Hypotension or Hypertension
- Myocardial infarction
- Pseudoaneurysm formation
- Renal Insufficiency or Renal Failure
- Restenosis of the stented artery
- Page 7 of 38

- Stent migration
- Stent thrombosis
- Stroke, TIA, or other cerebrovascular accident
- Vessel injury, including perforation, trauma, rupture, and dissection
- Vessel occlusion

#### Clinical Studies

# BSC MELODIE Clinical Trial Safety Data

study period were due to cardiovascular causes (3), cancer (5), and respiratory patients with Target Lesion Revascularizations, no distal embolization, and no deaths were adjudicated as device or procedure related. The nine deaths that occurred during the Major Adverse Events as adjudicated by an independent Clinical Events Committee: 13 24 months post-index procedure. Figure 1 displays the Kaplan-Meier curve of Freedom from Major Adverse Events through the end of the study. Thirteen patients (10.2%) had enrolled subjects were included in the analysis. Table 2 presents the principal A total of 152 subjects at 10 centers were treated in this prospective, single-arm study. insufficiency (1). effectiveness and safety results for the MELODIE trial through completion of the study at One subject was de-registered and excluded from the analysis because a signed consent form was not in place prior to the study index procedure. Therefore, a total of 151

Table 2. Principal Effectiveness and Safety Results
All Treated Subjects (N=151)

(101-N) stanfone narparr IIV		
Effectiveness and Safety Measures	(N=151 subjects) (N=163 lesions)	[95% CI]
Ellectiveness Measures	(1, 10, 11, 11, 11, 11, 11, 11, 11, 11, 1	
Lesion Based		
Angiographic Mean Percent Loss of Lumen Diameter at 6 Months	16.2±18.4 (112) (-18.5, 100.0)	[12.8, 19.6]
Angiographic Binary Restenosis at 6 Months	5.6% (7/124)	[2.3%, 11.3%]
Angiographic Percent Diameter Stenosis at 6 Months	24.3±16.0 (124) (-9.5, 100.0)	[21.5, 27.1]
CTA Target Lesion Patency at 12 Months	97.2% (103/106)	[92.0%, 99.4%]
CTA Target Lesion Patency at 24 Months	94.1% (95/101)	[87.5%, 97.8%]
Technical Success	98.0% (147/150)	94.3%, 99.6%
Procedural Success?	97.1% (136/140)	192.8%, 99.2%]
Clinical Success <sup>3</sup>		
30 Days	88.2% (127/144)	[81.8%, 93.0%]
6 Months	83.1% (108/130)	[75.5%, 89.1%]
12 Months	82.5% (99/120)	[74.5%, 88.8%]
Limb Based	10.0 /8 (00/110)	(10.1 m, 00.5 m)
Hemodynamic Success*		
30 Days	70.3% (110/150)	07.7%, 81.9%
6 Months	71.2% (94/132)	(62.7%, 78.8%)
12 Months	60.2% (71/118)	[50.7%, 69.1%]
24 Months	57.9% (66/114)	[48.3%, 67.1%]
Safety Measures		
Target Lesion Revascularization		
In-Hospital	0.6% (1/163)	[0.0%, 3.4%]
30 Days	0.6% (1/163)	[0.0%, 3.4%]
6 Months	6.5% (10/154)	[3.2%, 11.6%]
12 Months	9.0% (13/145)	[4.9%, 14.8%]
24 Months	10.3% (14/136)	[5.7%, 16.7%]
End of Study	10.3% (14/136)	5.7%, 16.7%
In-Hospital Major Adverse Events (MAE)	0.7% (1/151)	0.0%, 3.6%]
Device/Procedure Related Death	0.0% (0/151)	[0.0%, 2.4%]
TLR	0.7% (1/151)	[0.0%, 3.6%]
Oistal Embolization	0.0% (0/151)	[0.0%, 2.4%]
Major Adverse Events (MAE) through 30 Days	0.7% (1/151)	0.0%, 3.6%
TI O	0.0% (0/151)	0.0%, 2.4%
Distal Embolization	0.0% (0/151)	0.0%, 0.0%
Major Adverse Events (MAE) through 6 Months	6.3% (9/144)	2.9%, 11.5%)
Device/Procedure Related Death	0.0% (0/144)	0.0%, 2.5%)
TLR	6.3% (9/144)	
Distal Embolization	0.0% (0/144)	[0.0%, 2.5%]
Major Adverse Events (MAE) through 12 Months	8.9% (12/135)	[4.7%, 15.0%]
Device/Procedure Related Death	0.0% (0/135)	[0.0%, 2.7%]
TER	8.9% (12/135)	4.7%, 15.0%]

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Distal Embolization	0.0% (0/135)	[0.0%, 2.7%]
Major Adverse Events (MAE) between 24 Months	10.2% (13/127)	[5.6%, 16.9%]
Device/Procedure Related Death	0.0% (0/127)	[0.0%, 2.9%]
TLR	10.2% (13/127)	[5.6%, 16.9%]
Distal Embolization	0.0% (0/127)	[0.0%, 2.9%]
Major Adverse Events (MAE) through End of Study	10.2% (13/127)	[5.6%, 16.9%]
Device/Procedure Related Death	(751/0) %0.0	[0.0%, 2.9%]
TLR	10.2% (13/127)	[5.6%, 16.9%]
Distal Embolization	0.0% (0/127)	[0.0%, 2.9%]
Non-MAE Death		
Through 210 days	1.4% (2/144)	[0.2%, 4.9%]
Through 365 days	2.2% (3/137)	[0.5%, 6.3%]
Through 730 days	5.3% (7/131)	[2.2%, 10.7%]
Through End of Study	6.9% (9/131)	[3.2%, 12.6%]

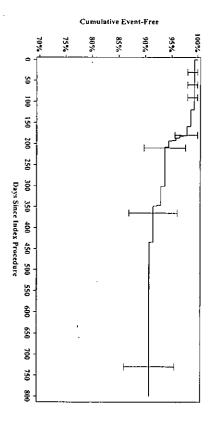
Through End of Study

\* All measurements taken after a confirmed TLR are excluded from this table.

Technical Success - successful delivery and deployment of the study stent to the target tesion with < 30% residual stenosis as determined by argiography. 
Stenosis as determined by argiography. 
Procedural Success - Technical Success without the occurrence of Major Adverse Events during the procedure and 
immediately post-procedure until discharge.

\*\*Clinical Success - an improvement of the Fontaine classification by at least one class compared to the pre-procedure 
\*\*Clinical Success - an improvement of the Fontaine classification by at least one class compared to the pre-procedure

Figure 1. Freedom from Major Adverse Events (CEC Adjudicated) to End of Study Event-Free Survival ± 1.96 SE, All Treated Subjects (N=151)



Intervals are inchesive or interval 180 is defined as 01.180 days inchesive	Std Error	Event Free	Events/Month	Events	At Risk	Censored	Entered	(N = 151 Subjects)
interval t	0.7%	99.3%	30.0	_	151	0	151	0
n defeat	0.7%	99.3%	0.0	0	149.5	1	150	30
ar 01.180	0.7%	99.3%	0.0	0	147	4	149	60
200	0.7%	99.3%	0.0	0	144.5	1	145	90
5	1.2%	20.86	0.7	2	143.5	1.	144	180
	2.0%	93.7%	6.0	6	138	6	141	210
	2.3%	%5.16	0.6	3	127.5	3	129	365
	2.4%	90.7%	0.1		97.5	51	123	730
	:	1	0.0	0	35.5	71	71	End of Study

Entered: # subjects eligible at the start of the interval.

Censored: # subjects censored during the interval.

At risk is # entered - half of # censored in the time interval

Events: # subjects with events in the interval.

Survival rate estimates are from the Kaplan-Meier method, reported at each interval's end.

The standard error was calculated using Greenwood's formula

BSC MELODIE Clinical Trial

(OPC) representative of the Palmaz® balloon-expandable stent months post-stent implantation is non-inferior to an objective performance criterion occlusive atherosclerotic disease (de novo or restenotic lesions) in the iliac arteries effectiveness of the Express LD Stent implantation in the treatment of stenosed or Objective: The primary objective of the study was to obtain information on the safety and (common or external), and to demonstrate that the mean % loss of luminal diameter at six

Design: The MELODIE study was a prospective, single-arm, multicenter study conducted at 10 centers enrolling a total of 152 subjects. Subjects had chronic

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anticoagulation or antiplatelet therapy, intraluminal thrombus of the proposed treated Express LD Stents. Subjects with uncorrected bleeding disorders, contraindications to was required to be  $\leq 10$  cm long and treatable with a maximum of two overlapping with baseline percent diameter stenosis  $\geq$  50% by visual estimate. The diseased segmen symptomatic (Fontaine class IIa, IIb, or III) atherosclerotic disease in the iliac arteries from the study lesion(s) post thrombolytic therapy, or known allergy to stainless steel were excluded

subject, Plavix® (clopidogrel) 75 mg once daily was administered until the end of the medications, if indicated study. Subjects were also permitted to take additional anticoagulant/antiplatelet up phase of the study. If use of Aspirin® (acetylsalicylic acid) was contraindicated for a (acetylsalicylic acid) 100 mg administered once daily during the entire 24-month followthe participating study center. After the procedure, subjects were to receive Aspirin® antiplatelet treatment according to the routine practice of the participating study center Before the stenting procedure, subjects were administered anticoagulant and/or During the procedure, the use of heparin was permitted according to routine practice at

follow-up was done at 12 and 24 months. follow-up was performed at 6 months and computed tomography angiography (CTA) months, for a total follow-up period of 24 months post-index procedure. Angiographic Follow-up included office visits at 30 days, 6 months (primary endpoint), 12 and 24

luminal diameter at 6 months post-procedure based on angiographic core lab assessment Endpoints: The primary endpoint of this study was angiographic mean percent loss of

# Secondary and tertiary endpoints included:

- technical success of  $\leq$  30% residual stenosis immediately post-procedure with successful stent delivery and deployment
- procedural success of technical success without major adverse events during the procedure and immediately post-procedure, until hospital discharge
- hemodynamic success of improved ABI by  $\geq 0.1$  above pre-procedure value and not deteriorated by >0.15 from the maximum post-procedure value at discharge, 30 days, 6 months, 12 months, and 24 months.
- months, and 24 months. class compared to the pre-procedure classification at 30 days, 6 months, 12 clinical success of an improvement of the Fontaine classification by at least one
- angiographic binary restenosis as stenosis of the target lesion > 50% of the reference vessel diameter at the time of assessment at 6 months
- angiographic percent diameter stenosis post-procedure at 6 months
- target lesion revascularization (TLR) at discharge, 30 days, 6 months, 12 months and 24 months.
- major adverse events (MAEs) defined as device- and/or procedure-related death; target vessel revascularization; distal embolization related to the device requiring

hospitalization and/or subsequent intervention at discharge, 30 days, 6 months, 12 months, and 24 months.

computer tomography angiography (CTA) target lesion patency post-procedure defined as the proportion of treated lesions with percentage diameter stenosis of the target lesion  $\geq 50\%$  of the reference vessel diameter at the time of assessment at 12 and 24 months.

The primary endpoint is met if the angiographic mean percent loss of luminal diameter for the Express LD Stent is statistically significantly lower than the objective performance criterion (OPC) representative of the Palmaz® balloon-expandable stent of 15% plus a non-inferiority margin of 5% (20.0%), ("Stenting of the Iliac arteries with the Palmaz® stent: Experience from a multicenter trial", Palmaz J et al., Cardiovascular Intervention Radiology 1992; 15: 291-297].

Demographics: Baseline characteristics of the MELODIE clinical trial showed 74.8% were males. The average age was 60.1 (range 43 to 84 years), 12.6% had medically treated diabetes, 54.4% had a history of hyperlipidemia, 60.3% had hypertension, and 87.4% were current or previous smokers. Baseline lesion characteristics included mean reference vessel diameter (RVD) of 7.9 mm, mean minimum lumen diameter (MLD) of 3.3 mm, mean percent diameter stenosis (%DS) of 62.9%, and mean lesion length of 32.0 mm.

Table 3. Baseline Demographic Characteristics
All Treated Subjects (N=151)

Characteristic	(N =151 subjects)	[95% CI]
Demographics		
Maie	74.8% (113/151)	67.1%, 81.5%)
Female	25.2% (38/151)	[18.5%, 32.9%]
Age (yr)	60.1±8.4 (151) (43.0, 84.5)	[58.8, 61.5]
Risk factors		
Known Smoking, Ever	87.4% (132/151)	[81.0%, 92.3%]
Current	62.1% (82/132)	[53.3%, 70.4%]
Previous	37.9% (50/132)	[29.6%, 46.7%]
Known Medically Treated Diabetes	12.6% (19/151)	[7.7%, 19.0%]
Insulin Requiring	6.0% (9/151)	[2.8%, 11.0%]
Non-insulin Requiring	6.6% (10/151)	[3.2%, 11.8%]
Hypertension	60.3% (91/151)	[52.0%, 68.1%]
Hyperlipidemia	54.4% (80/147)	46.0%, 62.6%
Comorbidities		
History of Myocardial Infarction	22.0% (33/150)	[15.7%, 29.5%]
Angina Pectoris	14.7% (22/150)	[9.4%, 21.4%]
Stroke or Transient Ischemic Attack	7.3% (11/151)	[3.7%, 12.7%]
Renal Disease	1.3% (2/151)	[0.2%, 4.7%]
Chronic Obstructive Pulmonary Disease	8.7% (13/150)	[4.7%, 14.4%]
Previous treatment of atherosclerotic lesions in the iliac artery	10.7% (16/149)	[6.3%, 16.9%]
Previous vascular surgical intervention in legs	13.9% (21/151)	[8.8%, 20.5%]
Other Disease	28.5% (43/151)	21.4%, 36.4%]
Platelet count (x10²)	234.0±59.4 (143)	[224.3, 243.8]
	(115.0, 420.0)	

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Characteristic	(N =151 subjects)	[95% CI]
Claudication		
>1000 meters	1.3% (2/150)	[0.2%, 4.7%]
200 ~ 1000 meters	15.3% (23/150)	[10.0%, 22.1%]
< 200 meters	83.3% (125/150)	[76.4%, 88.9%]
Tissue Loss		
Right leg	0.0% (0/145)	[0.0%, 2.5%]
Left leg ·	0.0% (0/145)	[%5.2 ,%0.0]

Table 4. Baseline Lesion Characteristics Determined by QVA
All Target Lesions (N=163) in All Treated Subjects (N=151)

,		•
Characteristic	(N = 163 lesions)	[95% CI]
Target Lesion Location		
Right Common Iliac Artery	22.1% (36/163)	[16.0%, 29.2%]
Right Common Iliac Artery Extending Into External	3.1% (5/163)	[1.0%, 7.0%]
Right External Iliac Artery	19.0% (31/163)	[13.3%, 25.9%]
Left Common iliac Artery	(591/15) %0.61	[13.3%, 25.9%]
Left Common Iliac Artery Extending Into External	3.7% (6/163)	[1.4%, 7.8%]
Left External Iliac Artery	33.1% (54/163)	[26.0%, 40.9%]
Minimum Lumen Diameter (MLD, mm)	3.3±1.4 (99) (0.0, 8.2)	[3.0, 3.5]
Reference Vesset Diameter (RVD, mm)	7.9±1.6 (99) (5.0, 13.3)	[7.5, 8.2]
Mean Lumen Diameter (mm)	6.9±1.4 (99) (4.0, 11.9)	[6.7, 7.2]
Percent Diameter Stenosis (%DS)	62.9±19.3 (116) (30.2, 100.0)	[59.4, 66.4]
Target Lesion Length (mm)	32.0±21.7 (99) (3.9, 99.1)	[27.7, 36.3]

Methods: Clinical follow-up was conducted in-hospital, and at 30 days, 6 months, 12 and 24 months post-procedure. Follow-up angiography at 6 months was performed in 81.3% of the subjects. Follow-up CT angiography was performed in 83.1% of the subjects at 12 months, and in 83.8% of the subjects at 24 months. Angiographic and CTA data were assessed by quantitative analysis by a core laboratory. An independent Clinical Events Committee adjudicated Major Adverse Events.

Results: All subjects enrolled in the MELODIE trial received an Express LD stent. Procedural success was achieved in 97.1% of subjects, with technical success achieved in 98.0% of lesions. The four procedural failures were due to the residual percent diameter stenosis ≥ 30% (technical failures) in three subjects and the occurrence of one major adverse event before discharge. The three technical failures were due to residual percent diameter stenosis between 31.2% and 33.1% measured by QVA.

The mean percent luminal diameter loss at six months was 16.2%±18.4% for the Express LD stent. This result was statistically significantly lower (P=0.0061) than the OPC plus delta (15% + 5% = 20%) with an upper 95% confidence bound of 18.7%, demonstrating non-inferiority compared to the Palmaz stent for the treatment of atherosclerotic lesions in the iliac artery.

Table 5. Primary Endpoint: Angiographic Mean % Loss of Luminal Diameter All Treated Lesions (N=163) in All Treated Subjects (N=151)

* All measurements taken after a confirmed TLR are	Angiographic Mean % Loss of Luminal Diameter		
R are excluded from this table.	16.21±18.42	(N = 112 paired lesions)	
	15.0±16.0	Literature OPC	
	5.0	Delta	
	0.0061	p-value	

Table 6. Principal Effectiveness
All Treated Subjects (N=151)

Effectiveness Measure	(N=151 subjects) (N=163 lesions) (N=159 limbs)	[95% CI]
Lesion Based		
Angiographic Mean Percent Loss of Lumen Diameter at	16.2±18.4 (112)	[52.8. 10.6]
6 Months	(-18.5, 100.0)	[12.0, 13.0]
Angiographic Binary Restenosis at 6 Months	5.6% (7/124)	[2.3%, 11.3%]
Angiographic Percent Diameter Stenosis at 6 Months	24.3±16.0 (124) (-9.5, 100.0)	[21.5, 27.1]
CTA Target Lesion Patency at 12 Months	97.2% (103/106)	[92.0%, 99.4%]
CTA Target Lesion Patency at 24 Months	94.1% (95/101)	[87.5%, 97.8%]
Technical Success	98.0% (147/150)	[94.3%, 99.6%]
Subject Based		
Procedural Success	97.1% (136/140)	[92.8%, 99.2%]
Clinical Success		
30 Days	88.2% (127/144)	[81.8%, 93.0%]
6 Months	83.1% (108/130)	[75.5%, 89.1%]
12 Months	82.5% (99/120)	[74.5%, 88.8%]
24 Months	78.8% (89/113)	[70.1%, 85.9%]
Limb Based		
Hemodynamic Success		
In-Hospital	75.3% (116/154)	[67.7%, 81.9%]
30 Days	79.3% (119/150)	[72.0%, 85.5%]
6 Months	71.2% (94/132)	[62.7%, 78.8%]
12 Months	60.2% (71/118)	[50.7%, 69.1%]
24 Months	57.9% (66/114)	[48.3%, 67.1%]

Table 7. Summary of Secondary and Tertiary Endpoints All Treated Subjects (N=151)

s and Safety Measures  (N=151 subjects) (N=152 limbs)  5 Measures  (N=153 limbs)  5 Measures  (N=153 limbs)  5 Measures  (N=159 limbs)  5 Measures  6 Months  6 J 2% (10316)  7 2% (10316)  9 2.7%, 10316)  9 2.7%, (10316)  9 2.7%, 10316)  9 2.7%, 10316)  9 2.8%, 24 3±16 0 (124) (21.5) 27.2% (10316)  9 2.7%, 10316)  9 2.7%, 10317)  9 3.7%, 10317)  10 2%, 10 3%			
25/5 (7/124) 25/5 (7/124) 26/5 (7/124) 27/5 (00/104) 27/5 (00/105) 27/5 (00/106) 27/5 (00/106) 27/5 (00/106) 27/5 (00/106) 27/5 (10/106) 27/5	Effectiveness and Safety Measures	(N=151 subjects) (N=163 lesions) (N=159 timbs)	[95% CI]
biss at 6 Months 5.6% (7/124)  24.3±16.0 (124) (-9.5, 100.0)  24.12 Months 97.2% (103/106)  27.2% (103/106)  27.4% (103/106)  27.4% (103/106)  27.4% (103/106)  27.4% (103/106)  27.5% (103/106)	Effectiveness Measures		
55% (7/124) 55% (7/124) 24.34-16.0 (124) 1dr Stenosis et 6 Months 24.34-16.0 (124) 24.54-16.0 (124) 24.54-16.0 (124) 24.54-16.0 (124) 24.54-16.0 (124) 24.54-16.0 (124) 24.54-16.0 (124) 25.2% (137/144) 25.2% (137/144) 25.2% (137/144) 25.2% (137/144) 25.2% (137/120) 25.2%	Lesion Based		
ter Stenosis at 6 Months  24.3±16.0 (124) 24.5±10.0)  81.24 Months  97.25 (103/106)  97.15 (103/106)  97.15 (103/106)  97.15 (103/106)  97.15 (103/106)  98.25 (127/144)  88.25 (197/30)  88.25 (197/30)  88.25 (197/30)  88.25 (197/30)  88.25 (197/30)  78.35 (197/30)  78.35 (197/30)  78.35 (197/30)  78.37 (197/30)  78.37 (197/30)  78.37 (197/30)  78.37 (197/30)  57.37 (197/30)	Angiographic Binary Restenosis at 6 Months	5.6% (7/124)	[2.3%, 11.3%]
ai 12 Months 97.2% (103/106) ai 24 Months 94.1% (95/101) ai 24 Months 98.0% (147/150) 97.1% (136/144) 88.2% (127/144) 83.1% (108/130) 78.5% (19/150) 78.5% (19/150) 77.5% (19/150)	Angiographic Percent Diameter Stenosis at 6 Months	24.3±16.0 (124) (-9.5, 100.0)	[21.5, 27.1]
81.24 Months 94.1% (95/101) 96.0% (147/150) 97.1% (136/140) 97.1% (136/140) 88.2% (127/144) 88.7% (198/130) 98.5% (199/120) 78.3% (199/150) 78.3% (199/150) 78.3% (199/150) 78.3% (199/150) 78.3% (199/150) 78.3% (199/150) 78.3% (199/150) 78.3% (199/150) 78.3% (199/150) 78.3% (199/150) 78.3% (199/150) 78.3% (199/150) 78.4% (199/150) 78.4% (199/150) 78.4% (199/150) 78.4% (199/150) 78.4% (199/150) 78.4% (199/150) 78.4% (199/150) 78.4% (199/150) 78.4% (199/150) 78.4% (199/150) 78.4% (199/150) 78.4% (199/150)	CTA Target Lesion Patency at 12 Months	97.2% (103/106)	[92.0%, 99.4%]
98.0% (147/150) 97.1% (136/140) 97.1% (136/140) 88.2% (127/144) 83.1% (168/130) 88.5% (99/120) 78.5% (99/120) 78.5% (99/120) 78.5% (99/120) 78.5% (19/150) 79.3% (119/150) 79.3% (119/150) 79.5% (19/150) 57.9% (99/14) 9.0% (19/151) 9.0% (19/151) 9.0% (19/151) 9.0% (19/151) 9.0% (19/151) 9.0% (19/151) 9.0% (19/151) 9.0% (19/151) 9.0% (19/151) 9.0% (19/151) 9.0% (19/151) 9.0% (19/151)	CTA Target Lesion Patency at 24 Months	94.1% (95/101)	[87.5%, 97.8%]
97.1% (139/140)  97.1% (139/140)  88.2% (127/144)  83.1% (199/130)  78.5% (199/130)  78.5% (199/130)  78.5% (199/130)  78.5% (199/130)  78.5% (199/130)  78.5% (199/130)  78.5% (199/130)  78.5% (199/130)  55.9% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)  5.5% (199/130)	Technical Success	98.0% (147/150)	94.3%, 99.6%]
97.1% (1367140) [92.8% 88.2% (1277144) [81.8% 83.1% (1060130) [75.5%, 82.5% (991720) [74.5%, 78.2% (991720) [74.5%, 79.3% (119150) [72.0%, 71.2% (941732) [62.7%, 60.2% (71171;8) [50.7%, 57.9% (681714) [48.3%, 57.9% (881714) [48.3%, 10.3% (141736) [0.0%, 10.3% (141736) [5.7%, 10.3% (141736) [5.7%, 10.3% (141736) [5.7%, 10.3% (141736) [5.7%, 10.2%, 137127) [0.0%, 10.2%, 137127) [0.0%, 10.2%, 137127) [0.0%,	Subject Based		
88.2% (1927144) [81.8% 83.1% (198730) [75.5% 82.5% (991720) [74.5% 78.5% (891720) [74.5% 78.5% (191750) [70.1% 78.5% (191750) [70.1% 78.5% (191750) [70.7% 77.2% (941732) [82.7% 80.2% (71118) [80.7% 80.5% (10163) [0.0% 90.5% (10163) [0.0% 90.5% (10164) [32.5% 90.5% (10154) [32.5% 90.5% (10154) [32.5% 90.7% (10151) [0.0% 90.7%	Procedural Success	97 1% (136/140)	[92.8%, 99.2%]
88.2% (1921/44) [81.8% 88.2% (1921/44) [81.8% 88.2% (1921/44) [75.5% 88.27% (1981/20) [74.5% 82.2% (1981/20) [70.1% 78.5% (891/13)] [70.1% 78.5% (891/13)] [70.1% 69.2% (711/11;8) [50.7% 69.2% (711/11;8) [50.7% 69.2% (1163) [0.0% 69.2% (1163)	Clinical Success		
83.1% (1984)30) [75.5% 82.5% (991/20) [70.1% 82.5% (991/20) [70.1% 82.5% (991/20) [70.1% 78.5% (119150) [70.1% 79.3% (119150) [72.0% 79.3% (119150) [72.0% 57.9% (891/12) [82.7% 57.9% (891/12) [82.7% 57.9% (891/12) [90.0% 57.9% (191/12) [90.0% 90.0% (191/12) [90.0%	30 Days	88.2% (127/144)	[81.8%, 93.0%]
82.5% (991720) [74.5% 78.5% (991721) [70.7% 78.5% (1918154) [67.7% 78.5% (1918154) [72.5% 71.2% (941732) [62.7% 60.2% (711118) [50.7% 57.5% (891141) [49.3% 57.5% (19184) [9.5% 9.5% (19184) [9.5% 10.5% (19184) [9.5% 10.5% (19184) [9.5% 10.5% (19184) [9.5% 10.5% (19184) [9.5% 10.5% (19184) [9.5% 10.5% (19185) [9.5% 10.5% (19185) [9.5% 10.5% (19185) [9.5% 10.5% (19185) [9.5% 10.5% (19185) [9.5%	6 Months	83.1% (108/130)	[75.5%, 89.1%]
78.5% (89/113) [70.1% 78.5% (19/154) [67.7% 79.3% (119/154) [72.5% 60.2% (71/118) [50.7% 60.2% (71/14) [48.3% 57.9% (86/114) [48.3% 57.9% (86/114) [49.3% 6.5% (10/154) [32/2% 10.3% (14/136) [5.7% 10.3% (14/136) [5.7% 10.3% (11/151) [0.0% 0.7% (11/151) [0.0% 0.7% (11/151) [0.0% 0.7% (11/151) [0.0% 0.7% (11/151) [0.0% 0.0% (13/157) [4.7% 10.2% (13/127) [5.6% 10.2% (13/127) [5.6%	12 Months	82.5% (99/120)	74.5%, 88.8%
55.3% (116/154) [67.7% 79.3% (119/150) [72.0% 79.3% (119/150) [72.0% 79.3% (119/150) [62.7% 60.2% (71/11;8) [62.7% 60.2% (13/163) [0.0% 57.9% (68/114) (48.3% 50.2% (13/164) [0.0% 6.5% (13/164) [0.2% 9.0% (13/164) [5.7% 9.0% (13/164) [5.7% 9.0% (13/164) [0.0% 0.0% (13/164) [0.0% 0.0% (13/165) [0.0% 0.0% (13/16	24 Months	78.8% (89/113)	[70.1%, 85.9%]
57.3% (116/154) [67.7% 79.3% (119/150) [72.0% 71.2% (94/132) [62.7% 60.2% (71/11) [62.7% 60.2% (71/11) [62.7% 60.2% (11/163) [0.0% 57.9% (68/114) [40.3% 0.6% (10/164) [3.2%, 9.0% (13/145) [0.0% 10.3% (14/136) [5.7%, 10.3% (14/136) [5.7%, 10.3% (14/136) [0.0% 6.3% (91/144) [2.9%, 10.2% (13/127) [2.9%, 10.2% (13/127) [5.6%,	Limb Based		
57.3% (116/354) [67.7% 77.3% (116/33) [62.7% 60.2% (71/11;8) [50.7% 60.2% (71/11;8) [50.7% 60.2% (71/11;8) [50.7% 60.2% (11/163) [0.0% 6.5% (10/164) [3.2% 6.5% (10/164) [3.2% 6.0% (13/145) [6.0% 6.0% (11/151) [0.0% 6.3% (11/151) [0.0% 6.3% (11/151) [0.0% 6.3% (11/151) [0.0% 6.3% (11/151) [0.0% 6.3% (11/151) [0.0%	Hemodynamic Success		
50.0% (119155) [72.0% 60.2% (71118) [50.7% 60.2% (71118) [50.7% 60.2% (11163) [0.0% 57.9% (66/114) (48.3% 57.9% (66/114) [3.2% 6.5% (10164) [3.2% 9.0% (33/145) [4.9% 10.0% (11161) [0.0% 10.0% (11161) [0.0% 6.5% (10164) [2.5%, 10.0% (11161) [0.0% 10.0% (11161) [0.0% 6.5% (10164) [3.2% 10.0% (11161) [0.0% 6.5% (10164) [3.2% 10.0% (11161) [0.0%	In-Hospital	75.3% (116/154)	[67.7%, 81.9%]
57.3% (94/132) (92.7% 60.2% (71/11;8) (50.7% 57.9% (68/14) (48.3% 57.9% (81/14) (48.3% 57.9% (17163) (0.0% 0.6% (17163) [0.0% 0.6% (17163) [0.0% 0.0% (17164) [4.7% 10.3% (14/136) [5.7% 0.7% (11/151) [0.0% 0.7% (17175) [0.0% 0.3% (17175) [4.7% 10.2% (13/127) [5.6%	30 Days	79.3% (119/150)	[72.0%, 85.5%]
50.2% (71/11:8) [50.7% 57.9% (69/114) [40.3% 57.9% (69/114) [40.3% 0.6% (1/163) [0.0% 0.6% (1/163) [0.0% 0.6% (1/163) [0.0% 10.0% (1/145) [5.7% 10.0% (1/1/15) [0.0% 0.7% (1/1/15) [0.0% 0.7% (1/1/15) [0.0% 0.3% (1/1/135) [4.7% 10.2% (1/1/127) [5.6%	6 Months	71.2% (94/132)	[62.7%, 78.8%]
57.9% (66114)  57.9% (66114)  0.6% (1/163)  0.6% (1/163)  0.6% (3/145)  9.0% (3/145)  10.3% (14/136)  0.7% (1/151)  0.7% (1/151)  0.3% (3/144)  8.9% (12/135)  10.2% (13/127)	12 Months	60.2% (71/11;8)	[50.7%, 69.1%]
bon 0.5% (1/163)   0.0%	24 Months	57.9% (66/114)	[48.3%, 67.1%]
550 0.6% (17163) [0.0% 0.6% (17163) [0.0% 0.6% (17163) [0.0% 0.6% (17163) [0.0% 0.6% (17164) [0.2% 0.0% (17145) [0.0% 0.7% (17151) [0.0% 0.7% (17151) [0.0% 0.7% (17151) [0.0% 0.7% (17151) [0.0% 0.2% (17155) [0.0% 0.2% (171	Safety Measures		
56n 0.5% (1/163) 10.0% 0.8% (1/163) 10.0% 0.8% (1/163) 10.0% 0.8% (1/163) 13.2% 10.0% (13/145) 14.9% 10.0% (13/145) 15.7% (14/136) 15.7% (14/136) 15.7% (14/136) 10.0% 0.7% (14/151) 10.0% 0.7% (14/151) 10.0% 0.2% (13/152) 14.7% 10.2% (13/127) 15.6%	Lesion Based		
0.6% (1163) [0.0% 0.6% (1163) [0.0% 0.5% (10164) [3.2% 0.0% (32145) [4.9% 10.3% (14136) [5.7% 10.2% (11151) [0.0% 0.7% (11151) [0.0% 0.7% (11151) [0.0% 0.7% (11151) [0.0% 0.7% (11151) [0.0% 0.7% (11151) [0.0% 0.0% (11151) [0.0% 0.0% (11151) [0.0% 0.0% (11151) [0.0%	Target Lesion Revascularization		
0.6% (1/163) [0.0% 0.0% (1/164) [3/2% 0.0% (1/164) [4.9% 10.3% (1/1/16) [5.7% 10.3% (1/1/16) [0.0% 0.7% (1/1/16) [0.0% 0.7% (1/1/16) [0.0% 0.3% (1/1/16) [0.0% 0.3% (1/1/16) [0.0% 0.3% (1/1/16) [0.0% 0.3% (1/1/16) [0.0% 0.3% (1/1/16) [0.0% 0.3% (1/1/16) [0.0%	in-Hospital	0.6% (1/163)	[0.0%, 3.4%]
8.5% (10/154) [3.2% 9.0% (13/145) [4.9% 10.3% (14/136) [5.7%, 10.3% (14/136) [0.0% 0.7% (11/151) [0.0% 0.7% (11/151) [0.0% 6.3% (12/135) [4.7%, 10.2% (13/127) [5.6%	30 Days	0.6% (1/163)	[0.0%, 3.4%]
9.0% (13/145)   4.9%   10.3% (14/136)   5.7%   10.3% (14/136)   10.0%	6 Months	6.5% (10/154)	[3.2%, 11.6%]
10.2% (14/136) [5.7%,  0.7% (14/151) [0.0%,  0.7% (14/151) [0.0%,  0.7% (14/151) [0.0%,  0.3% (91/44) [2.9%,  10.2% (13/127) [5.6%,	12 Months	9.0% (13/145)	[4.9%, 14.8%]
0.7% (1/151) [0.0% 0.7% (1/151) [0.0% 0.7% (1/151) [0.0% 6.3% (9/144) [2.9%, 8.9% (12/135) [4.7%, 10.2% (13/127) [5.6%,	24 Months	10.3% (14/136)	5.7%, 16.7%
0.7% (11/51)   0.0% 0.7% (11/51)   0.0% 6.3% (91/44)   12.9% 8.9% (12/135)   (4.7%, 10.2% (13/127)   (5.6%,	Subject Based		
0.7% (1/151)   0.0% 0.7% (1/151)   0.0% 0.3% (9/144)   72.9% 8.5% (12/135)   (4.7%) 10.2% (13/127)   5.6%,	Major Adverse Events (MAE)		
0.7% (1/15)   10.0% 0.3% (9/14)   12.9%, 10.2% (13/12)   16.7%, 10.2% (13/127)   15.6%,	In-Hospital	0.7% (1/151)	[0.0%, 3.6%]
6.3% (9/144) [2.9%, 12/135] [4.7%, 15.6%, 13/127) [5.6%, 13/127)	30 Days	0.7% (1/151)	[0.0%, 3.6%]
s 8.9% (12/135) [4.7%, s 10.2% (13/127) [5.6%,	6 Months	6.3% (9/144)	[2.9%, 11.5%]
10.2% (13/127) [5.6%,	12 Months	8.9% (12/135)	
	24 Months	10.2% (13/127)	[5.6%, 16.9%]

All measurements taken after a confirmed TLR are excluded from this table.

## Retrospective Performance Goal

To assess further the safety and effectiveness of the Express LD Stent in the treatment of stenosed or occlusive atherosclerotic iliac artery disease, a composite safety and effectiveness performance goal was developed from contemporary literature, and retrospectively applied to the MELODIE data.

The endpoint for this retrospective performance goal is a composite of the following safety and effectiveness endpoints:

- procedure/device-related death to 30 days
- in-hospital MI
- TLR through 12 months (365 days)
- amputation of the target limb through 12 months (365 days)

Based on a review of the literature, the expected rate for this endpoint at 12 months was estimated to be 10%. Using a delta of 9%, the performance goal for this endpoint was 19%.

The observed rate of this endpoint in the MELODIE trial was 11.1% with a one-sided 95% upper confidence limit of 16.7% (see Table 8). This is lower than the performance goal of 19%, further supporting the safety and effectiveness of iliac stenting with the Express LD stent.

able 8. Analysis of 12-month Composite Safety and Effectiveness Endpoint for the MELODIE study
All Treated Patients (N=151)

Endpoint	(N=151 Patients)	One-sided 95% upper CI to test the performance goal*
12-Month MAE	11.1% (15/135)	16.7%
Procedure/device-related death to 30 days	0.0% (0/135)	
In-hospital MI	0.7% (1/135)	
TLR to 12 months	8.9% (12/135)	
Amputation to 12 months	2.2% (3/135)	

\* The hypotheses for testing the performance goal of 19% are:  $H_0$ :  $n \ge 19\%$  and  $H_1$ :  $\pi < 19\%$ , where  $\pi$  is the rate of 12-month MAE for the MELODIE study. To conclude the Express LD stent is significantly less than the performance goal, the one-sided 95% upper confidence interval under  $H_0$  from the MELODIE study must be less than 19%.

### Overlapping Stent Analysis

An analysis was completed comparing outcomes in subjects with overlapping stents to those without. Twenty-seven subjects in the MELODIE study had overlapping stents placed. Table 9 shows the number of subjects that had overlapping stents by overlap configuration.

57 mm	37 mm	27 mm	25 mm	Stent Size	Table 9. Quantit
:	:	_	0	27 mm	y or Overlapping
ſ	œ	2	. 1	37 mm	rable at Quantity of Overlapping Stent Configurations
7	7	1	0	57 mm	Hons

Table 10 displays outcomes in MELODIE subjects treated with overlapping stents compared to those without overlapping stents. In general, outcomes in patients treated with overlapping stents are similar to outcomes in patients not treated with overlapping stents. Technical, procedural and hemodynamic success endpoints were very similar between the two groups. There were no device or procedure related deaths and no instances of distal embolization in either group. Any conclusions drawn from Table 10

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must be interpreted with caution as the MELODIE study was not designed or powered to compare outcomes in patients with and without overlapping stents. It is generally known that there is a trend for more MAEs, particularly TVR, in patients with overlapped stents and longer lesions in the peripheral arteries, just as is seen in the coronary arteries.

Table 10: Principal Effectiveness and Safety Results, Patients with overlapping stents versus patients with no overlapping stents

(N=127 limbs) (120 cm) (N=127 limbs) (120 cm) (N=127 limbs) (N=127 limbs		Subjects with overlapping stents (N=27 subjects)	riapping stents	Subjects with no overlapping stents (N=124 subjects)	/ertappin
18.3±22.4 (26)   19.7, 26.9    15.6±17.1 (66)   (-18.5, 100.0)   (-18.3, 100.0)   (-18.3, 100.0)   (-18.3, 100.0)   (-18.3, 100.0)   (-18.5, 100.0)   (-18.3, 100.0)   (-18.5, 100.0)   (-18.3, 100.0)   (-18.5, 100.0)   (-18.5, 100.0)   (-18.5, 100.0)   (-18.5, 100.0)   (-19.5,	Effectiveness Measures		,		ĺ
18.3±27.4 (26)   19.7, 26.9    15.5±17.1 (86)   1-18.5, 100.0    11.1% (427)   12.4%, 29.2%    4.1% (497)   11.1% (427)   28.2±19.3 (27)   70.9, 35.5    23.2±14.8 (97)   28.2±19.3 (27)   70.9, 35.5    23.2±14.8 (97)   28.2±19.3 (27)   70.8%, 98.9%  99.9%  99.5% (7680)   90.9% (7022)   70.8%, 98.9%  99.3% (715/118)   90.5% (7322)   80.8%, 99.9%  99.3% (715/118)   90.5% (7322)   77.20%, 98.9%  81.3% (87107)   90.5% (7921)   90.5%, 98.9%  81.3% (87107)   90.5% (7922)   77.20%, 98.9%  81.3% (87107)   90.5% (7922)   77.20%, 98.9%  77.3% (87107)   90.5% (7923)   77.1%, 99.9%  77.3% (7093)   95.0% (7923)   77.1%, 99.9%  73.8% (901722)   80.3% (25.23)   77.26%, 93.8%  99.3%  77.3% (7093)   95.0% (7923)   77.9% (77.8%, 97.7%)   86.3% (54.9%)   99.3% (70.9%)   77.9% (77.9%)   77.	Lesion Based		,		
(-18.5, 100.0) (-18.5	Angiographic Mean Percent Loss of Lurnen	18.3±22.4 (26)	19.7 26.91	15.6±17.1 (86)	112.0
11.1% (327) [2.4%, 29.2%] 4.1% (497) 28.2±19.3 (27) [20.9, 35.5] (-5.5, 10.0) [88.10.0) [70.8%, 98.9%] 98.8% (93.84) 90.9% (2072) [70.8%, 98.9%] 98.3% (115/118) 96.9% (21/32) [80.4%, 99.9%] 97.4% (111/114) 96.2% (23/25) [80.4%, 99.9%] 97.4% (111/114) 96.2% (23/25) [80.4%, 99.9%] 97.4% (111/114) 96.5% (23/25) [80.4%, 99.9%] 97.4% (111/114) 96.5% (23/25) [80.5%, 98.8%] 80.8% (90/92) 91.3% (23/25) [80.5%, 98.8%] 80.8% (90/92) 91.3% (25/22) [80.5%, 98.8%] 73.8% (90/122) 81.3% (25/22) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/22) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/122) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/124) 81.3% (25/23) [80.5%, 92.8%] 73.8% (90/124) 81.3% (25/23) [80.5%, 92.8%] 90.8% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.8% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.8% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.8% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.8% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.8% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.9% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.9% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.9% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.9% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.9% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.9% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.9% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.9% (11/24) 81.3% (25/23) [80.5%, 92.8%] 90.9% (11/24) 81.3%	Claireter at 0 Months	{-16.5, 100.0J		(-16.3, 100.0)	
28.2±19.3 (27) (20.9, 35.5) (23.2±14.8 (97) (86.100.0) 90.9% (20.72) (70.8%, 98.9%; 98.8% (83.98) 90.5% (19.27) [86.6%, 98.8%; 98.9%] 98.8% (83.98) 90.5% (19.27) [86.6%, 98.8%; 99.9%] 99.3% (115/118) 96.2% (25/26) [80.4%, 99.9%] 97.4% (111/114) 92.0% (23/25) [74.0%, 99.9%] 81.3% (87/07) 91.3% (21/23) [72.0%, 98.9%] 81.3% (87/07) 90.5% (19/21) [83.6%, 98.8%] 80.8% (80/99) 91.3% (25/23) [83.5%, 92.8%] 73.8% (80/12) 80.6% (25/23) [83.5%, 92.8%] 73.8% (80/12) 91.3% (25/23) [83.5%, 92.8%] 73.8% (80/12) 91.3% (72/23) [83.5%, 92.8%] 73.8% (80/12) 91.2% (17.2%) [83.5%, 92.8%] 73.8% (80/12) 91.2% (17.2%) [83.5%, 92.8%] 73.8% (80/12) 91.2% (17.2%) [83.5%, 92.8%] 73.8% (80/12) 91.2% (17.2%) [83.5%, 92.8%] 73.8% (80/12) 91.2% (17.2%) [83.5%, 92.8%] 73.8% (80/12) 91.2% (17.2%) [83.5%, 92.8%] 73.8% (80/12) 91.2% (17.2%) 91.2% (17.	Angiographic Binary Restenosis at 6 Months	11.1% (3/27)	[2.4%, 29.2%]	4.1% (4/97)	11.1%
(8.8, 100.0) (8.8,	Angiographic Percent Diameter Stenosis at 6	28.2±19.3 (27)	709 3551	23.2±14.8 (97)	963
90.5% (2022) [70.8%, 90.9%] 90.8% (90.8%) 90.5% (1921) 69.5%, 81.8%] 99.9%] 90.5% (116/118) 90	Months	(8.8, 100.0)	[20.0, 00.0]	(-9.5, 100.0)	100
90.5% (1921) [66.5%, 98.8%] 95.0% (7680) 96.9% (31/32) [83.8%, 99.9%] 96.3% (11/3/18) 96.2% (25/25) [80.4%, 99.9%] 97.4% (11/11/14) 96.2% (25/25) [80.4%, 99.9%] 97.4% (11/11/14) 97.2% (25/25) [74.0%, 99.0%] 87.4% (10/41/19) 97.3% (21/22) [72.0%, 98.9%] 87.3% (80/99) 97.3% (21/22) [72.0%, 98.9%] 87.3% (80/99) 97.3% (10/21) [83.5%, 92.8%] 73.8% (90/122) 87.3% (10/21) [83.5%, 92.8%] 73.9% (90/122) 87.3% (76/23) [71.8%, 97.7%] 88.3% (80/99) 89.3% (25/23) [71.8%, 97.7%] 88.3% (80/99) 89.3% (25/23) [71.8%, 97.7%] 88.3% (80/99) 89.3% (73.9% (10/23) [71.8%, 97.7%] 88.3% (80/99) 89.3% (73.9% (10/23) [71.8%, 97.7%] 88.3% (80/99) 17.2% (40/31) [3.5%, 23.8%] 56.8% (11/29) 17.2% (40/31) [3.5%, 23.8%] 56.8% (11/29) 17.2% (40/31) [5.5%, 33.7%] 7.0% (81/14) 18.7% (50/9) [5.5%, 34.7%] 8.5% (91/96) 18.7% (50/9) [5.5%, 34.7%] 8.5% (91/96) 16.7% (50/9) [5.5%, 34.7%] 8.5% (91/96) 16.7% (50/9) [5.5%, 34.7%] 8.5% (91/96) 16.7% (50/9) [5.5%, 34.7%] 8.5% (91/96) 16.7% (50/9) [5.5%, 34.7%] 0.0% (11/24) 0.0% (07/27) [0.0%, 12.8%] 0.0% (11/24) 0.0% (07/27) [0.0%, 12.8%] 0.0% (07/24) 0.0% (07/27) [0.0%, 12.8%] 0.0% (07/24) 0.0% (07/27) [0.0%, 12.8%] 0.0% (07/24) 0.0% (07/27) [0.0%, 12.8%] 0.0% (07/24) 0.0% (07/27) [0.0%, 12.8%] 0.0% (07/24)	CTA Target Lesion Patency at 12 Months	90.9% (20/22)	[70.8%, 98.9%]	98.8% (83/84)	193.5%
96.2% (25/26) [83.8%, 99.9%] 99.3% (116/118) 96.2% (25/26) [80.4%, 99.9%] 97.4% (111/114) 92.2% (23/25) [74.0%, 99.0%] 87.4% (111/114) 92.2% (23/25) [72.0%, 98.5%] 81.3% (90/107) 90.5% (19/27) [83.6%, 98.8%] 81.3% (90/107) 90.5% (19/27) [83.6%, 98.8%] 75.3% (70/93) 95.0% (19/20) [75.1%, 99.9%] 75.3% (70/93) 95.0% (19/20) [75.1%, 99.9%] 75.3% (70/93) 95.0% (19/20) [83.6%, 92.8%] 79.0% (94/119) 89.3% (25/23) [83.6%, 92.8%] 79.0% (94/119) 89.3% (25/23) [83.6%, 92.8%] 79.0% (94/119) 89.3% (25/23) [83.6%, 92.8%] 79.0% (94/119) 10.0% (0/24) [0.0%, 10.3%] 0.8% (1/29) 11.2% (4/31) [3.6%, 29.8%] 54.9% (50/91) 16.7% (5/30) [5.5%, 34.7%] 56.8% (9/102) 16.7% (5/30) [5.5%, 34.7%] 8.5% (9/106) 16.7% (5/30) [5.5%, 34.7%] 8.5% (9/104) 0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)	CTA Target Lesion Patency at 24 Months	90.5% (19/21)	[69.6%, 98.8%]	95.0% (76/80)	%2.78 <u>]</u>
96.2% (25/26) [80.4%, 99.9%] 97.4% (11/114) 92.0% (23/25) [74.0%, 99.9%] 87.4% (10/119) 92.0% (23/25) [74.0%, 99.9%] 87.4% (10/119) 93.3% (21/23) [72.5%, 98.9%] 81.3% (80/107) 90.5% (19/21) [85.6%, 98.8%] 81.8% (80/99) 95.0% (19/21) [75.1%, 99.9%] 75.3% (70/93) 95.0% (25/22) [83.5%, 92.5%] 79.9% (94/119) 12.9% (16/23) [71.5%, 99.9%] 76.3% (54/93) 12.9% (16/23) [92.5%, 92.5%] 79.9% (94/119) 10.9% (10/34) [0.0%, 10.3%] 0.8% (14/29) 10.9% (10/34) [0.0%, 10.3%] 0.8% (14/29) 11.9% (14/11) [3.6%, 29.8%] 4.9% (64/23) 11.9% (14/21) [3.6%, 29.8%] 4.9% (64/23) 116.7% (5/30) [5.5%, 34.7%] 8.5% (9/106) 16.7% (5/30) [5.5%, 34.7%] 8.5% (9/106) 16.7% (5/30) [5.5%, 34.7%] 0.0% (11/24) 10.0% (0/27) [0.0%, 12.8%] 0.0% (11/24) 10.0% (0/27) [0.0%, 12.8%] 0.0% (11/24) 10.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 10.0% (0/27) [0.0%, 12.8%] 0.0% (11/24) 10.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 10.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)	Technical Success	96.9% (31/32)	[%6.66 %8.68]	(811/911) %5.86	%0'r6l
96.2% (25/25) [80.4%, 99.9%] 97.4% (111/14) 96.2% (25/25) [74.0%, 99.9%] 87.4% (104/119) 97.3% (27/23) [72.0%, 88.9%] 81.3% (87/107) 99.5% (19/21) [86.5%, 98.8%] 80.8% (80/98) 95.0% (19/21) [86.5%, 98.8%] 75.3% (70/93) 81.3% (25/22) [83.5%, 92.8%] 75.9% (94/119) 80.5% (25/21) [82.5%, 92.8%] 75.9% (94/119) 80.5% (25/21) [82.5%, 92.8%] 79.9% (94/119) 80.5% (10/22) [71.8%, 97.7%] 86.3% (69/104) 7/3.9% (17/23) [71.8%, 97.7%] 86.3% (69/104) 7/3.9% (17/23) [71.8%, 97.7%] 86.3% (69/104) 173.9% (17/23) [71.8%, 80.8%] 56.9% (54/95) 18.5% (0/34) [0.0%, 10.3%] 0.8% (11/29) 17.2% (4/31) [3.5%, 29.8%] 4.9% (61/23) 17.2% (4/31) [5.5%, 33.7%] 7.9% (8/11/4) 18.7% (5/30) [5.5%, 34.7%] 8.5% (9/106) 18.7% (5/30) [5.5%, 34.7%] 8.5% (9/106) 18.7% (5/30) [5.5%, 34.7%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)	Subject Based				
92.0% (23/25) [74.0%, 99.0%] 87.4% (104/119) 91.3% (21/23) [72.0%, 98.9%] 81.3% (87/107) 90.5% (19/21) [63.6%, 98.8%] 80.8% (80/99) 95.0% (19/21) [63.6%, 92.8%] 75.8% (90/122) 81.3% (25/32) [63.6%, 92.8%] 79.0% (94/119) 89.3% (25/32) [63.6%, 92.8%] 79.0% (94/119) 89.3% (25/32) [63.6%, 92.8%] 79.0% (94/119) 89.3% (25/23) [63.6%, 92.8%] 79.0% (94/119) 89.3% (25/28) [71.8%, 93.8%] 54.9% (50/93) 17.9% (10/23) [63.6%, 10.3%] 0.8% (11/29) 0.0% (0/24) [0.0%, 10.3%] 0.8% (11/29) 17.9% (4/31) [3.6%, 29.8%] 4.9% (61/23) 18.1% (5/30) [5.5%, 34.7%] 8.5% (91/06) 16.7% (5/30) [5.5%, 34.7%] 8.5% (91/06) 16.7% (5/27) [0.0%, 12.8%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)	Procedural Success	96.2% (25/26)	[80.4%, 99.9%]	(111/111) %4.78	%5.26l
92.0% (23/25) [74.0%, 99.0%] 87.4% (104/119) 91.3% (21/23) [72.5%, 88.9%] 81.3% (80/107) 90.5% (19/21) [68.5%, 98.9%] 81.3% (80/107) 90.5% (19/21) [68.5%, 98.9%] 75.3% (70/93) 95.0% (19/20) [75.1%, 99.9%] 75.3% (70/93) 81.3% (25/32) [63.5%, 92.5%] 79.0% (94/119) 80.5% (25/32) [63.5%, 92.5%] 79.0% (94/119) 80.5% (25/32) [63.5%, 92.5%] 79.0% (94/119) 80.5% (25/32) [63.5%, 92.5%] 79.0% (94/119) 80.5% (25/32) [63.5%, 92.5%] 79.0% (94/119) 80.5% (16/23) [63.5%, 92.5%] 79.0% (10/24) 80.0% (10/24) [0.0%, 10.3%] 0.8% (11/29) 90.0% (10/24) [0.0%, 10.3%] 0.8% (11/29) 90.5% (10/24) [0.0%, 10.3%] 0.8% (11/24) 90.5% (10/27) [0.0%, 12.8%] 0.8% (11/24) 90.5% (07/27) [0.0%, 12.8%] 0.8% (11/24) 90.5% (07/27) [0.0%, 12.8%] 0.0% (01/24) 90.5% (07/27) [0.0%, 12.8%] 0.0% (01/24) 90.5% (07/27) [0.0%, 12.8%] 0.0% (01/24) 90.0% (07/27) [0.0%, 12.8%] 0.0% (01/24) 90.0% (07/27) [0.0%, 12.8%] 0.0% (01/24) 90.0% (07/27) [0.0%, 12.8%] 0.0% (01/24)	Clinical Success				
91 3% (21/23) [72.0%, 98.9%] 81.3% (87/107) 90.5% (19/21) [86.5%, 98.8%] 80.8% (80/99) 95.0% (19/20) [75.1%, 99.9%] 75.3% (70/93) 95.0% (19/20) [75.1%, 99.9%] 75.3% (70/93) 95.0% (25/92) [83.5%, 92.8%] 73.8% (90/122) 81.3% (25/92) [83.5%, 92.8%] 78.9% (89/104) 17.9% (17/23) [81.5%, 89.8%] 56.3% (89/104) 17.9% (17/23) [1.5%, 89.8%] 56.3% (89/104) 17.9% (17/23) [1.5%, 89.8%] 56.3% (11/29) 0.0% (0/34) [0.0%, 10.3%] 0.8% (11/29) 10.9% (4/31) [3.5%, 29.8%] 4.9% (8/129) 112.9% (4/31) [3.5%, 29.8%] 4.9% (8/129) 16.1% (5/30) [3.5%, 33.7%] 7.0% (8/114) 16.7% (5/30) [3.5%, 34.7%] 8.5% (9/106) 16.7% (5/30) [3.5%, 34.7%] 8.5% (9/106) 16.7% (6/27) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)	30 Days	92.0% (23/25)	[74.0%, 99.0%]	(911/101) 187.78	%1.08j
90.5% (19/21) [93.6%, 93.8%] 80.8% (20/98) 93.0% (19/20) [75.1%, 99.9%] 75.3% (70/93) 81.3% (25/92) [83.5%, 92.8%] 73.8% (90/122) 81.3% (25/92) [83.5%, 92.8%] 73.8% (90/122) 80.5% (25/92) [83.5%, 92.8%] 73.9% (94/119) 89.3% (25/28) [71.8%, 97.7%] 86.3% (69/104) 73.9% (17/23) [51.6%, 89.8%] 56.8% (54/95) 99.6% (19/23) 17.2% (63/3) [0.0%, 10.3%] 0.8% (11/29) 17.2% (4/31) [0.0%, 10.3%] 0.8% (11/29) 17.2% (4/31) [0.5%, 33.7%] 0.8% (11/29) 17.2% (69/10) [55/8, 33.7%] 7.0% (8/144) 16.7% (5/20) [55/8, 34.7%] 8.5% (9/106) 16.7% (5/20) [55/8, 34.7%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)	6 Months	91.3% (21/23)	[72.0%, 98.9%]	81.3% (87/107)	72.6%
95.0% (19/20) [75.1%, 99.9%] 75.3% (7093)  81.3% (25/32) [83.6%, 92.8%] 73.8% (90/172)  81.3% (25/32) [83.6%, 92.8%] 73.8% (90/172)  88.3% (25/32) [83.6%, 92.8%] 79.0% (94/19)  88.3% (25/32) [83.6%, 92.8%] 79.0% (94/19)  88.3% (25/32) [83.6%, 92.8%] 98.8% (54/85)  17.9% (17/23) [81.6%, 88.8%] 54.9% (50/91)  10.0% (0/24) [0.0%, 10.3%] 0.8% (1/129)  10.0% (0/24) [0.0%, 10.3%] 0.8% (1/129)  11.2% (4/31) [3.6%, 29.8%] 4.9% (6/123)  16.7% (5/31) [5.5%, 34.7%] 8.5% (9/166)  16.7% (5/30) [5.5%, 34.7%] 8.5% (9/166)  16.7% (5/30) [5.5%, 34.7%] 8.5% (9/166)  16.7% (6/27) [0.0%, 12.8%] 0.8% (1/124)  0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124)  0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124)  0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)  0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)  0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)  0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)	12 Months	90.5% (19/21)	[69.6%, 98.8%]	(96,08) %8.08	%2.t.d
81.3% (25/32) [83.6%, 92.8%] 73.8% (90/122) 80.6% (25/31) [82.5%, 92.8%] 79.0% (94/119) 80.3% (25/28) [71.8%, 92.7%] 68.3% (69/04) 73.9% (17/23) [51.6%, 89.8%] 64.9% (54/95) 69.6% (67/3) [47.1%, 86.8%] 64.9% (54/95) 10.0% (03/4) [0.0%, 10.3%] 0.8% (17/29) 10.0% (03/4) [0.0%, 10.3%] 4.9% (67/23) 16.7% (5/31) [3.6%, 29.8%] 4.9% (67/23) 16.7% (5/31) [5.5%, 33.7%] 7.0% (81/14) 16.7% (5/30) [5.5%, 34.7%] 8.5% (91/05) 16.7% (9/27) [0.0%, 12.8%] 0.6% (17/24) 10.0% (07/27) [0.0%, 12.8%] 0.0% (07/24) 10.0% (07/27) [0.0%, 12.8%] 0.0% (07/24) 10.0% (07/27) [0.0%, 12.8%] 0.0% (07/24)	24 Months	95.0% (19/20)	[75.1%, 99.9%]	75.3% (70/93)	%2.59 <u>]</u>
81.3% (2532) [63.5%, 92.8%] 73.8% (90/122) 80.6% (2523) [62.5%, 92.5%] 79.0% (94/119) 83.3% (25/28) [71.8%, 97.7%] 66.3% (69/104) 73.9% (17/23) [51.5%, 89.8%] 56.8% (54/85) 69.5% (16/22) [47.1%, 66.8%] 56.8% (17/29) 0.0% (0/34) [0.0%, 10.3%] 0.8% (17/29) 10.0% (0/34) [0.0%, 10.3%] 0.8% (17/29) 112.9% (4/31) [3.6%, 29.8%] 4.9% (67/22) 16.1% (5/31) [5.5%, 33.7%] 7.0% (97/14) 16.1% (5/31) [5.5%, 34.7%] 8.5% (97/06) 16.7% (5/30) [5.5%, 34.7%] 8.5% (97/06) 16.7% (6/27) [0.0%, 12.8%] 0.8% (17/24) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/724) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/724)	Limb Based	-			
81.3% (25/32) [83.5%, 92.8%] 73.8% (90/122) 80.5% (25/31) [82.5%, 92.8%] 73.9% (94/119) 80.3% (25/31) [82.3%, 92.5%] 73.9% (64/119) 80.3% (25/31) [82.5%, 92.5%] 86.3% (64/119) 80.3% (17/22) [51.6%, 80.8%] 86.3% (64/19) 173.9% (17/22) [51.6%, 80.8%] 86.3% (64/19) 10.0% (0/24) [0.0%, 10.3%] 0.8% (1/129) 10.0% (0/24) [0.0%, 10.3%] 0.8% (1/129) 10.0% (0/24) [0.0%, 10.3%] 4.9% (8/129) 11.2% (4/31) [3.6%, 29.8%] 4.9% (8/129) 11.2% (4/31) [3.6%, 29.8%] 7.0% (8/114) 16.1% (5/30) [5.5%, 34.7%] 8.5% (9/106) 16.7% (5/30) [5.5%, 34.7%] 8.5% (9/106) 16.7% (5/30) [5.5%, 34.7%] 8.5% (9/106) 16.7% (5/27) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)	Hemodynamic Success				
80.6% (2523) [62.5%, 92.5%] 79.0% (94119) 89.3% (2528) [71.8%, 91.7%] 68.3% (69404) 73.9% (1723) [51.6%, 89.8%] 56.8% (5498) 69.6% (1623) [47.1%, 86.8%] 54.9% (5091) 0.0% (034) [0.0%, 10.3%] 0.8% (1129) 0.0% (034) [0.0%, 10.3%] 0.8% (1129) 12.9% (431) [3.6%, 29.8%] 4.9% (6123) 16.1% (523) [5.5%, 33.7%] 7.0% (8114) 16.1% (523) [5.5%, 33.7%] 7.0% (8114) 16.7% (520) [5.5%, 34.7%] 8.5% (9106) 16.7% (520) [5.5%, 34.7%] 8.5% (9106) 16.7% (520) [5.6%, 34.7%] 0.8% (1124) 0.0% (027) [0.0%, 12.8%] 0.8% (1124) 0.0% (027) [0.0%, 12.8%] 0.8% (1124) 0.0% (027) [0.0%, 12.8%] 0.8% (1124) 0.0% (027) [0.0%, 12.8%] 0.8% (1124) 0.0% (027) [0.0%, 12.8%] 0.8% (1124) 0.0% (027) [0.0%, 12.8%] 0.8% (1124)	In-Hospital	81.3% (26/32)	[63.6%, 92.8%]	73.8% (90/122)	%0'59
89.3% (25/28) [71.8%, 97.7%] 68.3% (69/104) 173.9% (17/23) [51.5%, 98.8%] 54.9% (50/93) 69.6% (16/23) [47.1%, 86.8%] 54.9% (50/93) 69.6% (03/4) [0.0%, 10.3%] 0.8% (11/29) 0.0% (03/4) [0.0%, 10.3%] 0.8% (11/29) 17.9% (4/31) [3.6%, 29.8%] 4.9% (6/123) 17.9% (4/31) [5.5%, 33.7%] 7.0% (8/14) 18.7% (5/30) [5.5%, 34.7%] 8.5% (9/106) 19.7% (5/30) [5.5%, 34.7%] 8.5% (9/106) 19.7% (5/30) [5.5%, 34.7%] 8.5% (9/107) 10.0% (0/27) [0.0%, 12.8%] 0.8% (11/24) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.9% (0/124)	30 Days	80.6% (25/31)	[62.5%, 92.5%]	79.0% (94/119)	70.6%
73.9% (1772) [51.6%, 88.8%] 56.8% (54.95) 69.6% (1672) [47.1%, 86.8%] 54.9% (59.91) 0.0% (07.4) [0.0%, 10.3%] 0.8% (17.29) 0.0% (07.4) [0.0%, 10.3%] 0.8% (17.29) 10.0% (07.4) [0.0%, 10.3%] 0.8% (17.29) 10.0% (07.4) [5.5%, 33.7%] 7.0% (87.14) 16.7% (57.0) [5.5%, 34.7%] 8.5% (97.06) 16.7% (57.0) [5.5%, 34.7%] 8.5% (97.06) 16.7% (57.0) [5.5%, 34.7%] 8.5% (97.06) 10.0% (07.7) [0.0%, 12.8%] 0.8% (17.24) 0.0% (07.7) [0.0%, 12.8%] 0.8% (17.24)	6 Months	89.3% (25/28)	[71.8%, 97.7%]	66.3% (69/104)	56.4%
69.5% (16/23) [47.1%, 86.8%] 54.9% (50/91)  0.0% (0/34) [0.0%, 10.3%] 0.8% (17.29)  12.9% (4/31) [3.6%, 29.8%] 4.9% (67/23)  16.7% (5/31) [5.5%, 33.7%] 7.0% (8/114)  16.7% (5/32) [5.5%, 34.7%] 8.5% (9/106)  16.7% (5/32) [5.5%, 34.7%] 8.5% (9/106)  16.7% (5/32) [5.5%, 34.7%] 8.5% (9/106)  16.7% (5/32) [5.5%, 34.7%] 0.8% (11/24)  0.0% (0/27) [0.0%, 12.8%] 0.8% (11/24)  0.0% (0/27) [0.0%, 12.8%] 0.8% (11/24)  0.0% (0/27) [0.0%, 12.8%] 0.8% (11/24)  0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)  0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)  0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)  0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124)	12 Months	73.9% (17/23)	[51.6%, 89.8%]	56.8% (54/95)	[46.3%
0.0% (0721)	24 Months	69.6% (16/23)	[47.1%, 86.8%]	54.9% (50/91)	[44.2%
0.0% (0.24)	Safety Measures				
0.0% (0/34)   0.0%, 10.3%  0.8% (1/129)   0.0% 0.0% (0/34)   0.0%, 10.3%  0.8% (1/129)   0.0% 12.9% (4/31)   (3.6%, 29.8%  4.9% (6/123)   1.8%, 16.1% (5/31)   (5.5%, 33.7%  7.0% (8/114)   31.1%, 16.7% (5/30)   (5.5%, 34.7%  8.5% (9/106)   4.0%, 16.7% (5/30)   (5.5%, 34.7%  8.5% (9/106)   4.0%, 0.0% (0/27)   (0.0%, 12.8%  0.0% (0/124)   (0.0%, 0.0% (0/27)   (0.0%, 12.8%  0.0%) (0/124)   (0.0%)	Lesion Based				
0.0% (0.034)   10.0% (10.3%)   0.08% (11725)   10.0%   0.0% (0.34)   10.0%, 10.3%   0.08% (11725)   10.0%   12.9% (4.37)   13.6%, 29.88%   4.9% (61723)   11.8%,   16.1% (5/31)   15.5%, 23.7%   7.0% (8/114)   31.1%,   16.7% (5/31)   15.5%, 33.7%   7.0% (8/114)   31.1%,   16.7% (5/32)   15.5%, 34.7%   8.5% (9/106)   4.0%,   16.7% (5/32)   15.5%, 34.7%   8.5% (9/106)   4.0%,   10.0% (0/27)   10.0%, 12.8%   0.0% (1/124)   10.0%,   10.0% (0/27)   10.0%, 12.8%   0.0% (1/124)   10.0%,   10.0% (0/27)   10.0%, 12.8%   0.0% (1/124)   10.0%,   10.0% (0/27)   10.0%, 12.8%   0.0% (0/124)   10.0%,   10.0% (0/27)   10.0%, 12.8%   10.0% (0/124)   10.0%,   10.0% (0/27)   10.0%, 12.8%   10.0% (0/124)   10.0%,   10.0% (0/27)   10.0%, 12.8%   10.0% (0/124)   10.0%,	Target Lesion Revascularization				
0.0% (054)   0.0%, 10.3%   0.6% (1/125)   0.0%   10.0%	In-Hospital	0.0% (0/34)	[0.0%, 10.3%]	0.8% (1/129)	%0.0J
12.9% (4/31)	30 Days	0.0% (0/34)	[0.0%, 10.3%]	0.8% (1/129)	%0.0J
16.1% (5/31) (5.5%, 33.7%) 7.0% (8/114) [3.1%, 15.7% (5/30) (5.5%, 34.7%) 8.5% (9/106) (4.0%, 16.7% (5/30) (5.5%, 34.7%) 8.5% (9/106) (4.0%, 16.7% (5/30) (5.5%, 34.7%) 8.5% (9/106) (4.0%, 16.7% (5/30) (5.5%, 34.7%) 8.5% (9/106) (4.0%, 16.7% (5/30) (5.5%, 34.7%) 8.5% (9/106) (4.0%, 16.7% (5/30) (5.5%, 34.7%) 8.5% (9/106) (5.0%, 16.7%) 8.5% (9/106) 8.5% (9/	6 Months	12.9% (4/31)	[3.6%, 29.8%]	4.9% (6/123)	[1.8%,
16.7% (5/30) (5.6%, 34.7%) 8.5% (9/106) 16.7% (5/30) (5.6%, 34.7%) 8.5% (9/106) 16.7% (5/30) (5.6%, 34.7%) 8.5% (9/106) 16.7% (9/27) (0.0%, 12.8%) 0.8% (1/124) 0.0% (0/27) (0.0%, 12.8%) 0.6% (1/124) 0.0% (0/27) (0.0%, 12.8%) 0.6% (1/124) 0.0% (0/27) (0.0%, 12.8%) 0.6% (1/124) 0.0% (0/27) (0.0%, 12.8%) 0.6% (1/124) 0.0% (0/27) (0.0%, 12.8%) 0.6% (1/124) 0.0% (0/27) (0.0%, 12.8%) 0.6% (1/124) 0.0% (0/124) 0.0% (0/124) 0.0% (0/124) 0.0% (0/124)	12 Months	16.1% (5/31)	[5.5%, 33.7%]	7.0% (8/114)	3.1%
16.7% (5/30) [5.5%, 34.7%] 8.5% (9/106) [4.0%, 0.0% (0/27)] [0.0%, 12.8%] 0.8% (1/124) [0.0% (0/27)] [0.0%, 12.8%] 0.8% (1/124) [0.0% (0/27)] [0.0%, 12.8%] 0.9% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.9% (1/124) [0.0% (0/27)] [0.0%, 12.8%] 0.9% (1/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0% (0/27)] [0.0%, 12.8%] 0.0% (0/124) [0.0% (0/27)] [0.0	24 Months	16.7% (5/30)	[5.6%, 34.7%]	8.5% (9/106)	[4.0%]
0.0% (027) [0.0%, 12.8%] 0.8% (1/124) 0.0% (027) [0.0%, 12.8%] 0.8% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124)	End of Study	16.7% (5/30)	[5.6%, 34.7%]	8.5% (9/106)	[4.0%
0.0% (027)	Subject Based				
0.0% (0/27) (0.0%, 12.8%) 0.0% (0/124) 0.0% (0/27) (0.0%, 12.8%) 0.8% (1/124) 0.0% (0/27) (0.0%, 12.8%) 0.0% (0/124) 0.0% (0/27) (0.0%, 12.8%) 0.0% (0/124) 0.0% (0/27) (0.0%, 12.8%) 0.0% (0/124) 0.0% (0/124) 0.0% (0/124) 0.0% (0/124) 0.0% (0/124) 0.0% (0/124) 0.0% (0/124) 0.0% (0/124)	In-Hospital Major Adverse Events (MAE)	0.0% (0/27)	[0.0%, 12.8%]	0.8% (1/124)	%0.0J
0.0% (027) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/124) 0.0% (0/124) 0.0% (0/124) 0.0% (0/124) 0.0% (0/127) [0.0%, 12.8%] 0.6% (1/124) 0.0% (0/127) [0.0%, 12.8%] 0.0% (0/124) 0.0% (0/127) [0.0%, 12.8%] 0.8% (1/124) 0.0% (0/124)	Device/Procedure Related Death	0.0% (0/27)	[0.0%, 12.8%]	0.0% (0/124)	<b>%</b> 0.0]
0.0% (0/27)	TLR	0.0% (0/27)	[88.21 ,%0.0]	0.8% (1/124)	<b>%</b> 0.0
0.0% (027)	Distal Embolization	0.0% (0/27)	[0.0%, 12.8%]	0.0% (0/124)	%0.0]
0.0% (0/27)   [0.0%, 12.8%]   0.0% (0/124)   0.0% (0/27)   [0.0%, 12.8%]   0.8% (1/124)	Major Adverse Events (MAE) through 30 Days	0.0% (0/27)	[0.0%, 12.8%]	0.8% (1/124)	10.0% 10.0%
0.0% (0/27) [0.0%, 12.8%] 0.8% (1/124)	Device/Procedure Related Death	0.0% (0/27)	[0.0%, 12.8%]	0.0% (0/124)	%0.0J
	TLR	0.0% (0/27)	[0.0%, 12.8%]	0.8% (1/124)	%0.0

All measurements taken after a confirmed TLR are excluded from this table

Conclusion: Overall, the MELODIE trial demonstrated the Express LD stent to be safe and effective in the treatment of stenosed or occlusive atherosclerotic iliac artery disease

### HOW SUPPLIED:

Store in a cool, dry dark place

Do not use if package is opened or damaged.

By" date shown on the label. Rotate inventory so that the catheters and other dated products are used prior to the "Use radiation. Excessive aging may cause the polymers used in these products to deteriorate. Do not store catheters where they are directly exposed to organic solvents or ionizing

Non-pyrogenic.

#### Contents:

- One (1) Express LD Iliac Premounted Stent System
   One (1) Electronic DFU Reference Card

# OPERATIONAL INSTRUCTIONS:

### Recommended Materials:

- Micropuncture<sup>TM</sup> kit
- .035 in. (0.89 mm) Guidewire of appropriate length
- Introducer/Guide sheaths of appropriate size and length, and equipped with a hemostatic
- Luer-lock Syringe [10 cc or greater for prepping the premounted stent system] 3 Way Stopcock
- Inflation device [20 cc or greater]

### Patient Preparation STENT PLACEMENT PROCEDURE

in an angiography/ fluoroscopy procedure room. Patient preparation and sterile precautions should be the same as for any PTA procedure. Angiography/fluoroscopy are necessary for appropriate vessel sizing, and angiographic magnification is suggested vessels must be sufficiently patent, to proceed with further intervention. Multiple views should be performed to map out the extent of the lesion(s) and the collateral flow. Access The percutaneous placement of the stent in a stenotic or obstructed artery should be done

# Select Proper Premounted Stent System

- premounted stent system length (refer to Table 1). 1. Estimate the distance between the lesion and the entry site to select the proper
- 2. Measure the diameter of the reference vessel to determine the appropriate diameter stent and delivery balloon (refer to Table 1).

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should approximate the diameter of the vessel just distal to the stenosis Note: To reduce the potential for vessel damage the inflated diameter of the balloon

3. Measure the length of the target lesion to determine the length of the stent required. Size the stent length to extend slightly proximal and distal to the lesion. The appropriate stent length should be selected based on covering the entire lesion with a single stent (refer to Table 1).

# Prepare the Premounted Stent System

- Do not use product after the "Use By" date indicated on the package.
- Open package and remove hoop with premounted stent system. before opening. Do not use if the integrity of the sterile package has been compromised. Open the box and remove the sterile package. Carefully inspect the sterile package
- 4. Remove the premounted stent system from the hoop. Remove the stent protector and
- Verify the stent is positioned between the proximal and distal balloon markers.

for bends, kinks and other damage. Do not use if any defects are noted Caution: Do not attempt to manually reposition the premounted stent in any way. Check

- Flush the premounted stent system guidewire lumen with heparinized normal saline.
- gaseous substance as a balloon inflation medium. medium is a 50/50 mixture of contrast medium and normal saline. Do not use air or any Prepare inflation device/syringe with diluted contrast medium. The standard inflation

Attach inflation device/syringe to stopcock. Attach to premounted stent system

Note: A 10 cc luer-lock syringe is recommended for use for aspirating this device.

- 9. Open stopcock to premounted stent system. With the distal balloon tip pointing down 30 seconds. Carefully release to neutral for contrast fill and placed below the level of the inflation device/syringe, pull negative pressure for 20
- 10. Close stopcock to the premounted stent system; purge inflation device/syringe of al
- 11. Repeat steps 9 and 10 until all air is expelled. If bubbles persist, do not use the
- 12. If a syringe was used for preparation, attach a prepared inflation device to stopcock

Note: A 20 cc Inflation device is recommended for use with this device

13. Open stopcock between the premounted stent system and the inflation device

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### Delivery Procedure

and procedure. Reference Table 1 for the minimum acceptable size for this device. Insert the appropriate sheath or guide catheter for the selected premounted stent system

balloon during tracking advisable to use a sheath or guide catheter that is long enough to cross the lesion. Use of a guide sheath or guide catheter minimizes the risk of dislodging the stent from the Caution: Always use an appropriately sized sheath for the implant procedure. It is

2. Advance a .035 in. (0.89 mm) guidewire of appropriate length across target lesion

procedure is complete to avoid having to regain access. Note: It is strongly recommended that the guidewire remain across the lesion until the

- 3. Pre-dilate the lesion as necessary with a balloon dilatation catheter of appropriate size using conventional techniques.
- After the lesion has been properly pre-dilated, remove the dilatation catheter.
- maintaining guidewire position across target lesion. 5. Backload the premounted stent system onto proximal portion of guidewire while
- advancing the premounted stent system into the vessel. or Y-adapter attached to the guide catheter. Ensure sheath/guide stability before Carefully advance the premounted stent system into the hemostasis valve of the sheath

sheath or guide catheter, do not force passage. Resistance may indicate a problem and Caution: If resistance is encountered to the premounted stent system prior to exiting the catheter as a single unit. placement across the lesion and remove the premounted stent system with sheath or guide may result in damage or dislodgement of the stent if forced. Maintain guidewire

Advance premounted stent system over the guidewire to target lesion under direct fluoroscopic visualization.

cause of resistance cannot be determined, withdraw both the premounted stent system Caution: If strong resistance is met during advancement of the premounted stent system, discontinue movement and determine the cause of the resistance before proceeding. If the and sheath or guide catheter as a single unit.

stent unless it is properly centered on the balloon and properly positioned within the is still centered within the marker bands and has not been dislodged. Do not deploy the sheath or guide catheter, as dislodgement of the stent from the balloon may occur. The attempt to pull a premounted stent system that has been partially expanded back into the carefully repositioned or removed. Removal of a stent that has not been expanded: Do not target lesion. If the position of the stent within the lesion is not optimal, it should be reference points to position the stent in the lesion. During positioning, verify that the stent Utilize the proximal and distal radiopaque markers as well as the radiopaque stent as premounted stent system should be withdrawn until the proximal end of the stent is

aligned with the distal tip of the sheath or guide catheter. The sheath or guide catheter and premounted stent system should be removed as one unit.

### Deployment Procedure

L. To deploy the stent, use an inflation device to slowly inflate the premounted stent system to at least the opening pressure shown in Table 1. Higher pressure may be necessary to optimize apposition against the lesion. Balloon pressures must not exceed rated burst pressure (12 atm /1216 kPa).

procedure is complete to avoid having to regain access. Note: It is strongly recommended that the guidewire remain across the lesion until the

device to ensure proper balloon rewrap. 2. After deploying the stent, slowly deflate the balloon manually using the inflation

Caution: Allow adequate time for the balloon to fully deflate prior to removal. Observe fluoroscopically that the balloon is fully deflated prior to removal.

Position the sheath or guide to a coaxial position with the balloon catheter.
 Maintaining proper sheath or guide catheter support, very slowly withdraw the balloon Observe under fluoroscopy to ensure that the balloon disengages from the stent.

before proceeding. fluoroscopy and conventional techniques to determine and remedy the cause of resistance Caution: If resistance is encountered upon attempted removal, do not force removal, use

the proximal and distal reference vessel diameter. be used in order to properly judge the optimum expanded stent diameter as compared to 5. Confirm stent position and deployment using angiographic techniques. For optimal results, the entire lesion should be covered by the stent. Fluoroscopic visualization should

appropriate size, to the stented area using standard angioplasty techniques. 6. If re-sizing is necessary, re-advance the SDS catheter, or another balloon catheter of

exceed the rated burst pressure. Do not expand the stent beyond maximum stent diameter as shown in Table 1. Deflate the balloon and follow the instructions as outlined in 7. While observing under fluoroscopy, inflate the balloon to the desired pressure; do not

"Deployment Procedure" steps 3 and 4.

8. Reconfirm stent position and angiographic result. Repeat inflations until the desired

9. While maintaining negative pressure in the balloon, remove the SDS from the body through the sheath or guide catheter.

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Table 11. Typical Express® LD Iliac Premounted Stent System Compliance

Pressure	Balloo	n Diam	Balloon Diameter (mm)	1)	
(atm-kpa)					
	6.0	7.0	8.0	9.0	10.0
	mm	mm	mm	mm	mm
6 - 608	5.79	6.69	7.60	8.67	9.57
7 - 709	5.83	6.76	7.70	8.75	9.69
8.0~811*	5.89*	6.85*	7.83*	8.87*	9.80
9.0 - 912	5.97	6.93	7.92	8.93	9.88
10.0 - 1013*	6.02	6.99	7.99	9.00	9.97*
11 - 1115	6.08	7.04	8.05	9.05	10.03
12 - 1216**	6.11	7.08	8.10	9.10	10.08
*Nominal Pressure	ssure				
**Rated Burst Pressure, DO NOT EXCEED	Pressure	DONO	)T EXCE	ED.	
User should confirm stent diameter angiographically during	onfirm ste	nt diam	eter angio	graphica	lly during

balloon inflation

#### WARRANTY:

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

Micropuncture is a registered trademark of Cook, Inc.

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# Express® LD Biliary

OVER - THE - WIRE Premounted Stant System

我 ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

#### WARNING:

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

#### DEVICE NAME:

Express LD Biliary Premounted Stent System.

### DEVICE DESCRIPTION:

The Express LD Biliary Premounted Stent System consists of:

A 316L surgical grade stainless steel balloon expandable stent. The stent is premounted on an over the wire Stent Delivery System (SDS) equipped with a non compliant balloon. The SDS balloon catheter has two radiopaque markers embedded in the shaft to aid in the placement of the stent. The SDS is compatible with 0.035 in (0.89 mm) guidewires. The SDS balloon has a maximum inflation pressure of 12 atm (1216 kPa) that can be used for, initial stent placement and post stent dilatation.

The Premounted Stent System is available in a variety of stent lengths with SDS balloons that expand them from 5 mm to 10 mm in diameter. The SDS balloon catheter is also offered in two shaft lengths. Table 1 summarizes individual product descriptions and nominal specifications.

Note: The diameter of the stent may be increased post-placement by expanding with a larger diameter balloon. Do not exceed the maximum expanded stent diameter.

# INTENDED USE/INDICATIONS FOR USE:

ncoplasms in the biliary tree. The Express LD Biliary Premounted Stent System is indicated for palliation of malignant

### CONTRAINDICATIONS:

System as a transhepatic endoprosthesis include: Contraindications associated with the use of the Express LD Biliary Premounted Stent

- Stenting of a perforated duct where leakage from the duct could be exacerbated by the
- Patients with bleeding disorders.

#### WARNINGS

- the balloon Use only diluted contrast medium for balloon inflation (typically a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium in
- the balloon may cause difficulty in deploying the stent and deflation of the balloon. Prepare Premounted Stent System per instructions given. Significant amounts of air in
- Do not exceed the maximum rated burst pressure.
- implant. Persons with allergic reactions to stainless steel may suffer an allergic response to the
- Do not expose the Premounted Stent System to organic solvents (i.e. alcohol)
- Overstretching of the duct may result in patient injury. approximate the diameter of the duct just proximal and distal to the stricture. To reduce the potential for patient injury, the inflated diameter of the balloon should
- distortion of the magnetic field The Express LD Biliary Stent may cause image artifacts with MRI scans due to
- Stenting across a bifurcation could compromise future diagnostic or therapeutic

#### PRECAUTIONS:

- The device is intended for use by physicians who have received appropriate training.
- performance of the device is suspect, it should not be used. The sterile packaging and device should be inspected prior to use. If sterility or Do not attempt to pull a stent that has not been expanded back through an introducer
- sheath, since dislodgment of the stent may result. If a stent that has not been expanded When treating multiple strictures, the stricture distal to the puncture site should be removed as a unit. needs to be removed, the introducer sheath and the Premounted Stent System should be
- eliminates the need to cross the proximal stent to achieve placement of the distal stent Inflation at a high rate can cause damage to the balloon. Use of a pressure monitoring Premounted Stent System or dislodging the stent from the SDS balloon. and reduces the chance for dislodging the proximal stent with the SDS balloon or initially stented, followed by stenting of the proximal stricture. Stenting in this order The Premounted Stent System is not designed for use with power injection systems.

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- Do not attempt to manually remove or adjust the stent on the SDS balloon.
- sheath than indicated on the label. The minimally acceptable introducer sheath French size is printed on the package label Do not attempt to pass the pre-mounted stent system through a smaller size introducer
- not advance or retract the catheter unless the balloon is fully deflated under vacuum. When catheters are in the body, they should be manipulated only under fluoroscopy. Do
- · Never advance the Premounted Stent System without the guidewire extending from the
- To ensure expansion of the premounted stent, inflate the Premounted Stent System to at adequately treat the stricture.

the stent. If the target stricture is not fully covered, use additional stents as necessary to Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of

- inflate the Premounted Stent System to nominal pressure as shown on the label. least the opening pressure as shown on the label. To assure nominal sizing of the stent,
- stent is not optimal, it should not be expanded. been damaged or dislodged during positioning. Expansion of the stent should not be undertaken if the stent is not appropriately positioned in the duct. If the position of the Prior to stent expansion, utilize high-resolution fluoroscopy to verify the stent has not
- may cause complications resulting in patient injury. result in patient injury. Incomplete deployment of the stent (i.e. stent not fully opened) Do not attempt to reposition a partially deployed stent. Attempted repositioning may
- extreme caution. Recrossing a previously deployed stent with adjunct devices must be performed with
- required. Standard surgical procedure is appropriate. In the event of complications (such as infections), surgical removal of the stent may be
- · When multiple stents are required, if placement results in metal to metal contact, stent materials should be of similar composition.

Table 1. Express® LD Biliary Premounted Stent System Specifications

Calimped   Calimeter   Calim	rable 1, Expre	1, Expresse LU	dillary	Fremo	unted St	Billary Premounted Stent System Specifications	m Specifi	cations	
Champion   Champion			Ballo	on Size	)	Stent	Rated	Max.	Minimum
Length   Cann   Cann	Product Code	Stent	Dia.	Length	Usable:	Pressure	Pressure	Stent	Sheath
17   5   20   75   8   8   11   12   12   12   12   12		(mm) Length	(mm)	(mm)	(cm) Length	RP 3	(FP)	(zumeter	Size (Fr
27         5         20         75         8 (811)         72 (72)(8)           37         5         40         75         8 (811)         72 (72)(8)           57         5         40         75         8 (811)         72 (72)(8)           57         5         40         75         8 (811)         72 (72)(8)           57         6         20         75         8 (811)         72 (72)(8)           57         6         20         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         10         20	H74938046520750	17	5	8	75	8 (811)	12 (1216)	9	6F(.085)
37         5         40         75         8 (811)         72 (72)           57         5         40         75         8 (811)         72 (72)           17         6         20         75         8 (811)         72 (72)           27         6         20         75         8 (811)         72 (72)           37         6         40         75         8 (811)         72 (72)           40         75         8 (811)         72 (72)         72 (72)           57         7         20         75         8 (811)         72 (72)           57         7         20         75         8 (811)         72 (72)           57         7         20         75         8 (811)         72 (72)           57         7         20         75         8 (811)         72 (72)           57         8         20         75         8 (811)         72 (72)           57         9         20         75         8 (811)         72 (72)           57         9         20         75         8 (811)         72 (72)           57         9         20         75         8 (811)         72 (72) </td <td>H74938046530750</td> <td>22</td> <td>UT</td> <td>00</td> <td>75</td> <td>8(811)</td> <td>12 (1216)</td> <td>9</td> <td>6F( 085)</td>	H74938046530750	22	UT	00	75	8(811)	12 (1216)	9	6F( 085)
57         5         60         75         8 (811)         72 (72)(8)           17         6         20         75         8 (811)         72 (72)(8)           27         6         20         75         8 (811)         72 (72)(8)           37         6         40         75         8 (811)         72 (72)(8)           57         6         40         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         7         20         75         8 (811)         72 (72)(8)           57         8         20         75         8 (811)         72 (72)(8)           57         9         40         75         8 (811)         72 (72)(8)           57         9         40         75         8 (811)         72 (72)(8)           57         9         40         7	H74938046540750	37	u	\$	75	8 (811)	12 (1216)	و	6F(.085)
17         6         20         75         8 (8)11         72 (12)(8)           27         6         30         75         8 (8)11         72 (12)(8)           57         6         40         75         8 (8)11         72 (12)(8)           57         6         40         75         8 (8)11         72 (12)(8)           57         7         20         75         8 (8)11         72 (12)(8)           57         7         20         75         8 (8)11         72 (12)(8)           57         7         40         75         8 (8)11         72 (12)(8)           57         7         40         75         8 (8)11         72 (12)(8)           57         8         50         75         8 (8)11         72 (12)(8)           57         8         50         75         8 (8)11         72 (12)(8)           57         9         40         75         8 (8)11         72 (12)(8)           57         9         40         75         9 (8)11         72 (12)(8)           57         9         40         75         9 (8)11         72 (12)(8)           57         10         40	H74938046560750	57	5	60	75	£(811)	12 (1216)	9	6F(.085)
27         6         30         75         8 (911)         72 (1278)           57         6         40         75         8 (911)         72 (1278)           57         6         40         75         8 (911)         72 (1278)           17         7         60         75         8 (911)         72 (1278)           27         7         40         75         8 (911)         72 (1278)           27         7         40         75         8 (911)         72 (1278)           27         7         40         75         8 (911)         72 (1278)           27         8         40         75         8 (911)         72 (1278)           27         8         40         75         8 (911)         72 (1278)           27         8         40         75         8 (911)         72 (1278)           27         8         40         75         8 (911)         72 (1278)           27         8         40         75         8 (911)         72 (1278)           27         8         40         75         10 (1013)         72 (1278)           27         8         40         75	H74938046620750	17	o.	20	75	1:18)8	12 (1216)	9	6F(.065)
37         6         40         75         8 (811)         12 (1216)           17         6         60         75         8 (811)         12 (1216)           17         7         20         75         8 (811)         12 (1216)           27         7         20         75         8 (811)         12 (1216)           27         7         20         75         8 (811)         12 (1216)           27         7         20         75         8 (811)         12 (1216)           27         8         20         75         8 (811)         12 (1216)           27         8         20         75         8 (811)         12 (1216)           27         8         20         75         8 (811)         12 (1216)           27         8         20         75         8 (811)         12 (1216)           27         8         20         75         8 (811)         12 (1216)           27         8         20         75         9 (811)         12 (1216)           27         9         20         75         9 (811)         12 (1216)           27         10         40         135	H74938046630750	27	6	36	5.2	411618	12 (1216)	9	6F(.085)
57         6         00         75         8 (81)         2 (12)(8)           27         7         20         75         8 (81)         1 (2)(2)(8)           27         7         20         75         8 (81)         1 (2)(2)(8)           37         7         40         75         8 (81)         1 (2)(2)(8)           57         7         60         75         8 (81)         1 (2)(2)(8)           57         8         40         75         8 (81)         1 (2)(2)(8)           57         8         40         75         8 (81)         1 (2)(2)(8)           57         8         40         75         8 (81)         1 (2)(2)(8)           57         9         40         75         8 (81)         1 (2)(2)(8)           57         9         40         75         10 (10)(1)         12)(2)(8)           57         9         40         75         10 (10)(1)         12)(2)(8)           57         10         40         75         10 (10)(1)         12)(2)(8)           57         9         40         135         8 (81)         12)(2)(16)           57         10         40	H74938046640750	37	6	0+	25	8 (811)	12 (1216)	9	6F(085) .
17 7 20 75 8(81) 2(218)  37 7 40 75 8(81) 12(218)  37 7 40 75 8(81) 12(218)  37 7 40 75 8(81) 12(218)  37 7 40 75 8(81) 12(218)  37 8 00 75 8(81) 12(218)  37 8 00 75 8(81) 12(218)  37 8 00 75 8(81) 12(218)  37 9 00 75 8(81) 12(218)  37 9 00 75 8(81) 12(218)  37 9 00 75 8(81) 12(218)  37 10 40 75 8(81) 12(218)  37 10 40 75 10(101) 12(218)  37 10 40 75 10(101) 12(218)  37 10 40 75 10(101) 12(218)  37 10 10 30 75 10(101) 12(218)  37 10 10 30 135 8(81) 12(218)  37 10 10 30 135 8(81) 12(218)  37 1 0 10 30 135 8(81) 12(218)  37 1 0 10 30 135 8(81) 12(218)  37 1 10 30 135 8(81) 12(218)	H74938046660750	57	6	89	75	8 (811)	12 (1216)	9	6F(.085)
27         7         30         75         8 (811)         2 (2 (22 (6)))           37         7         40         75         8 (811)         2 (2 (22 (6)))           57         7         40         75         8 (811)         12 (12 (6))           57         7         60         75         8 (811)         12 (12 (6))           57         8         40         75         8 (811)         12 (12 (6))           57         8         40         75         8 (811)         12 (12 (6))           57         9         40         75         8 (811)         12 (12 (6))           25         9         40         75         8 (811)         12 (12 (6))           25         10         40         75         8 (811)         12 (12 (6))           25         10         40         75         10 (10 (1))         12 (12 (6))           27         10         40         75         10 (10 (1))         12 (12 (6))           27         5         40         133         8 (811)         12 (12 (6))           27         6         40         133         8 (811)         12 (12 (6)           27         7	H74938046720750	17	7	20	75	8 (811)	12 (1216)	9	6F(.085)
37         7         60         75         8 (811)         12 (1228)           17         80         75         8 (811)         12 (1226)           17         8         20         75         8 (811)         12 (1226)           27         8         30         75         8 (811)         12 (1226)           37         8         40         75         8 (811)         12 (1226)           25         9         40         75         8 (811)         12 (1226)           25         9         40         75         8 (811)         12 (1226)           27         10         40         75         8 (811)         12 (1226)           27         10         40         75         10 (1031)         12 (1226)           27         10         40         75         10 (1031)         12 (1226)           27         5         40         133         8 (811)         12 (1226)           27         5         40         133         8 (811)         12 (1226)           27         6         40         133         8 (811)         12 (1226)           27         7         40         133         8	H74938046730750	27	7	33	75	8 (811)	12 (1216)	9	6F(.085)
57         7         60         75         8 (811)         22 (1216)           27         8         20         75         8 (811)         12 (1216)           27         8         20         75         8 (811)         12 (1216)           37         8         40         75         8 (811)         12 (1216)           37         8         40         75         8 (811)         12 (1216)           37         9         40         75         8 (811)         12 (1216)           57         9         60         75         10 (1013)         12 (1216)           25         10         20         75         10 (1013)         12 (1216)           27         10         40         75         10 (1013)         12 (1216)           27         10         40         75         10 (1013)         12 (1216)           27         5         40         133         8 (811)         12 (1216)           27         5         40         133         8 (811)         12 (1216)           27         6         30         133         8 (811)         12 (1216)           27         7         40	H74938046740750	37	7	â	75	8 (811)	12 (1215)	9	6F(.085)
17         8         20         75         6 (811)         12 (1226)           27         8         30         75         8 (811)         12 (1216)           37         8         40         75         8 (811)         12 (1216)           57         8         60         75         8 (811)         12 (1216)           57         9         40         75         8 (811)         12 (1216)           57         9         40         75         10 (1013)         12 (1216)           25         10         40         75         10 (1013)         12 (1216)           27         10         40         75         10 (1013)         12 (1216)           27         10         40         75         10 (1013)         12 (1216)           27         5         40         135         8 (811)         12 (1216)           27         5         40         135         8 (811)         12 (1216)           27         6         40         135         8 (811)         12 (1216)           27         7         40         135         8 (811)         12 (1216)           27         7         40 <td< td=""><td>H74938046760750</td><td>57</td><td>  -</td><td>8</td><td>35</td><td>8 (811)</td><td>12 (1216)</td><td>g</td><td>6F(,085)</td></td<>	H74938046760750	57	-	8	35	8 (811)	12 (1216)	g	6F(,085)
27         8         30         75         8 (811)         72 (1216)           57         8         40         75         8 (811)         72 (1216)           57         8         60         75         8 (811)         72 (1216)           32         9         60         75         8 (811)         72 (1216)           25         10         30         75         8 (811)         72 (1216)           25         10         40         75         10 (103)         72 (1216)           25         10         40         75         10 (103)         72 (1216)           27         10         40         75         10 (103)         72 (1216)           27         5         40         135         8 (811)         12 (1216)           27         5         40         135         8 (811)         12 (1216)           27         5         40         135         8 (811)         12 (1216)           27         6         40         135         8 (811)         12 (1216)           27         7         40         135         8 (811)         12 (1216)           27         7         40         13	H74938046820750	17	65	ន	75	8(811)	12 (1216)	9	6F( 085)
37         6         40         75         6(81)         12(1216)           55         8         60         75         8(81)         12(1216)           37         9         40         75         8(81)         12(1216)           57         9         60         75         8(81)         12(1216)           25         10         40         75         10(101)         12(1216)           25         10         40         75         10(101)         12(1216)           27         10         40         75         10(101)         12(1216)           27         5         40         133         8(81)         12(1216)           27         5         40         133         8(81)         12(1216)           27         6         20         133         8(81)         12(1216)           27         7         20         133         8(81)         12(1216)           27         7         20         133         8(81)         12(1216)           27         7         40         133         8(81)         12(1216)           27         7         40         133         8(81)	H74938046830750	27		8	15	8 (811)	12 (1216)	9	6F(.085)
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37         9         40         75         8 (811)         12 (1216)           57         9         60         75         8 (811)         12 (1216)           57         9         60         75         10 (1013)         12 (1216)           37         10         40         75         10 (1013)         12 (1216)           57         10         60         75         10 (1013)         12 (1216)           57         10         60         75         10 (1013)         12 (1216)           57         5         40         135         8 (811)         12 (1216)           57         5         40         135         8 (811)         12 (1216)           57         6         40         135         8 (811)         12 (1216)           57         6         40         135         8 (811)         12 (1216)           57         7         40         135         8 (811)         12 (1216)           57         7         40         135         8 (811)         12 (1216)           57         7         40         135         8 (811)         12 (1216)           57         7         40	H74938046920750	25	9 0	8 8	75	8 (811)	12 (1216)	= :	7F( 099)
57         9         60         75         6(6/11)         72(12)6)           25         10         30         75         10(10/31)         12(12)6)           57         10         40         75         10(10/31)         12(12)6)           57         10         40         75         10(10/31)         12(12)6)           57         10         60         75         10(10/31)         12(12)6)           77         5         40         133         8(811)         12(12)6)           57         6         20         133         8(811)         12(12)6)           57         6         40         133         8(811)         12(12)6)           57         6         40         133         8(811)         12(12)6)           57         6         40         133         8(811)         12(12)6           57         7         40         133         8(811)         12(12)6           57         7         40         133         8(811)         12(12)6           57         8         30         133         8(811)         12(12)6           57         8         30         133 <t< td=""><td>H74938046940750</td><td>37</td><td>و</td><td>å</td><td>75</td><td>8 (811)</td><td>12 (1216)</td><td>=</td><td>7F(.099)</td></t<>	H74938046940750	37	و	å	75	8 (811)	12 (1216)	=	7F(.099)
25 10 20 75 10(1013) 12(1216)  37 10 40 15 10(1013) 12(1216)  57 10 60 75 10(1013) 12(1216)  17 5 20 133 8(811) 12(1216)  27 5 40 133 8(811) 12(1216)  27 6 20 133 8(811) 12(1216)  27 6 20 133 8(811) 12(1216)  27 6 20 133 8(811) 12(1216)  27 6 20 133 8(811) 12(1216)  27 7 6 20 133 8(811) 12(1216)  27 7 20 133 8(811) 12(1216)  27 7 20 133 8(811) 12(1216)  27 7 20 133 8(811) 12(1216)  27 7 40 133 8(811) 12(1216)  27 7 40 133 8(811) 12(1216)  27 7 20 133 8(811) 12(1216)  27 8 9 133 8(811) 12(1216)  27 9 10 135 8(811) 12(1216)  27 1 13 20 133 8(811) 12(1216)  27 1 20 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 1 30 133 8(811) 12(1216)  27 2 30 133 8(811) 12(1216)  27 3 40 133 8(811) 12(1216)  27 3 5 60 133 8(811) 12(1216)  27 6 7 7 8 7 7 8 7 8 8 8 8 8 8 8 8 8 8 8	H74938046960750	57	9	8	75	8 (811)	12 (1216)	11	7F(.099)
37         10         40         25         10 (1013)         12 (1246)           17         5         20         135         8 (811)         12 (1246)           17         5         20         135         8 (811)         12 (1246)           27         5         30         135         8 (811)         12 (1246)           27         6         20         135         8 (811)         12 (1246)           27         6         30         135         8 (811)         12 (1246)           27         6         30         135         8 (811)         12 (1246)           27         7         20         135         8 (811)         12 (1246)           27         7         20         135         8 (811)         12 (1246)           27         7         20         135         8 (811)         12 (1246)           27         7         20         135         8 (811)         12 (1246)           27         7         20         135         8 (811)         12 (1246)           27         8         30         135         8 (811)         12 (1246)           27         8         30 <td< td=""><td>H74938046102070</td><td>25</td><td>ā</td><td>8</td><td>75</td><td>10 (1013)</td><td>12 (1216)</td><td>11</td><td>777(.099)</td></td<>	H74938046102070	25	ā	8	75	10 (1013)	12 (1216)	11	777(.099)
57         10         60         75         10 (013)         72 (1216)           27         5         20         133         8 (811)         12 (1216)           27         5         20         133         8 (811)         12 (1216)           57         5         40         133         8 (811)         12 (1216)           57         6         20         133         8 (811)         12 (1216)           57         6         40         133         8 (811)         12 (1216)           57         6         40         133         8 (811)         12 (1216)           57         7         20         133         8 (811)         12 (1216)           57         7         40         133         8 (811)         12 (1216)           57         7         40         133         8 (811)         12 (1216)           57         7         40         133         8 (811)         12 (1216)           57         8         40         135         8 (811)         12 (1216)           57         8         40         135         8 (811)         12 (1216)           57         8         40	H74938046104070	37	ā	ŧ	23	10(1013)	12 [1216]	=	7F(.099))
17   5   20   135   8   8   11   12   12   18     37   5   40   135   8   8   8   11   12   12   18     37   5   40   135   8   8   8   11   12   12   18     37   6   20   135   8   8   8   11   12   12   18     37   6   40   135   8   8   8   11   12   12   18     37   6   40   135   8   8   8   11   12   12   18     37   7   20   135   8   8   8   11   12   12   18     37   7   40   135   8   8   8   11   12   12   18     37   7   40   135   8   8   8   11   12   12   18     37   7   40   135   8   8   8   11   12   12   18     37   7   40   135   8   8   8   11   12   12   18     37   8   40   135   8   8   8   11   12   12   18     37   8   40   135   8   8   8   11   12   12   18     37   8   40   135   8   8   8   11   12   12   18     37   9   40   135   8   8   8   11   12   12   18     37   9   40   135   8   8   8   11   12   12   18     37   9   40   135   8   8   8   11   12   12   18     37   9   40   135   8   8   8   11   12   12   18     37   9   40   135   8   8   8   11   12   12   18     37   9   40   135   8   8   8   11   12   12   12     37   9   40   135   8   8   11   12   12   12     37   9   40   135   8   8   11   12   12   12     37   9   40   135   8   8   11   12   12   12     37   9   40   135   8   8   11   12   12   12     37   9   40   135   8   8   11   12   12   12     38   9   135   10   10   10   10   10     37   10   40   135   10   10   10     37   10   40   135   10   10   10     37   10   40   135   10   10   10     37   10   40   135   10   10   10     38   40   10   10   10   10     39   10   10   10   10   10     30   10   10   10   10   10     31   10   10   10   10   10     31   10   10   10   10   10     31   10   10   10   10   10     31   10   10   10   10     31   10   10   10   10   10     31   10   10   10   10   10     31   10   10   10   10   10     31   10   10   10   10   10     31   10   10   10   10   10     31   10   10   10   10   10     31   10   10   10   10   10     31   10   10   10   10   10     31   10   10   10   10   10     31   10   10   10	H74938046106070	57	5	8	75	10 (1013)	12 (1216)	11	7F(.086)
27         5         30         135         8 (811)         12 (1216)           57         5         40         133         8 (811)         12 (1216)           57         5         60         133         8 (811)         12 (1216)           17         6         20         133         8 (811)         12 (1216)           27         6         40         135         8 (811)         12 (1216)           27         7         20         135         8 (811)         12 (1216)           27         7         40         135         8 (811)         12 (1216)           27         7         40         135         8 (811)         12 (1216)           27         8         30         135         8 (811)         12 (1216)           27         8         30         135         8 (811)         12 (1216)           27         8         30         135         8 (811)         12 (1216)           27         8         30         135         8 (811)         12 (1216)           27         8         30         135         8 (811)         12 (1216)           27         8         30         1	H74938047520130	17	Ç.	20	135	8 (811)	12 (1216)	19	6F(.085)
37         5         40         135         8(811)         27(218)           17         6         20         135         8(811)         12(1216)           17         6         20         135         8(811)         12(1216)           27         6         30         135         8(811)         12(1216)           37         6         40         135         8(811)         12(1216)           27         7         20         135         8(811)         12(1216)           27         7         40         135         8(811)         12(1216)           27         7         40         135         8(811)         12(1216)           27         7         60         135         8(811)         12(1216)           27         8         20         135         8(811)         12(1216)           27         8         20         135         8(811)         12(1216)           27         8         40         135         8(811)         12(1216)           27         8         40         135         8(811)         12(1216)           27         8         40         135         8(811)<	H74938047530130	27	5	g	ž	B (811)	12 (1216)	9	6F(.085)
57         5         60         135         8(81)         2(1216)           17         6         20         135         8(81)         12(1216)           27         6         30         135         8(81)         12(1216)           37         6         40         135         8(81)         12(1216)           57         9         40         135         8(81)         12(1216)           27         7         40         135         8(81)         12(1216)           27         7         40         135         8(81)         12(1216)           27         7         40         135         8(81)         12(1216)           27         8         20         135         8(81)         12(1216)           27         8         40         135         8(81)         12(1216)           27         8         40         135         8(81)         12(1216)           27         8         40         135         8(81)         12(1216)           27         8         40         135         8(81)         12(1216)           27         9         40         135         8(81)         <	H74938047540130	37	5	40	135	8 (811)	12 (1216)	9	6F(.085)
17         6         20         135         8 girlly         12 [1216]           27         6         30         135         8 girlly         12 [1216]           37         6         40         135         8 girlly         12 [1216]           57         6         40         135         8 girlly         12 [1216]           57         7         20         135         8 [811]         12 [1216]           37         7         40         135         8 [811]         12 [1216]           57         7         40         135         8 [811]         12 [1216]           17         8         20         135         8 [811]         12 [1216]           27         8         40         135         8 [811]         12 [1216]           27         8         40         135         8 [811]         12 [1216]           27         8         40         135         8 [811]         12 [1216]           27         9         40         135         8 [811]         12 [1216]           25         9         40         135         8 [811]         12 [1216]           25         9         40         <	H74938047560130	57	5	8	នី	8 (811)	12 (1216)	9	6F(.085)
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# MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

Non-clinical testing has demonstrated the Express LD stent in single and overlapped conditions is MR Conditional. It can be scanned safely, immediately after placement of this implant, under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Spatial gradient field of 700 Gauss/cm or less
- Normal operating mode of the MR system and use of whole body transmit coils only.
- Maximum whole-body-averaged specific absorption rate (WBA-SAR) of 2 Watts/kilogram, (W/kg), for 15 minutes of scanning for patient landmarks above the
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below umbilicus (patient navel).

migration or heating. at field strengths other than 1.5 Tesla or 3 Tesla has not been performed to evaluate steni The Express LD stent should not migrate in this MRI environment. Non-clinical testing

## 3.0 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 128 MHz in a 3.0 Tesla Magnetom Trio, Siemens Medical Solutions MR system, software version Numaris/4, syngo MR A30. The testing was according to ASTM F2182 and the stents were in a scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was electromagnetic fields in MRI yielded the following maximal in vivo rises: 1.8 W/kg. The maximal in-vitro temperature rise was 4.0°C when the local SAR was (RF) heating. RF power was applied for 15 minutes and the conductivity of the phantom based on these non-clinical tests and computer simulation of the patient exposure to the temperature rise. Fractured stents exhibited similar heating. Predicted in-vivo heating location and orientation in the phantom that produced the worst case Radio Frequency

- For landmarks above the umbilicus the calculated temperature rise was 5.2°C with an of 2.0 W/kg and a continuous scan time of 15 minutes. uncertainty upper bound temperature of 6.6°C for a whole body average SAR value
- of 1.0 W/kg and a continuous scan time of 15 minutes. uncertainty upper bound temperature of 5.2°C for a whole body average SAR value For landmarks below the umbilious the calculated temperature rise was 4.1°C with an

perfusion in the tissue outside the stent. include the cooling effects due to blood flow in the lumen of the stent and blood The actual in vivo rise is expected to be less than these values as the calculations did not

## 1.5 Tesla Temperature Information

material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower 2.1 W/kg. The maximal in-vitro temperature rise was 2.2°C when the local SAR was heating. RF power was applied for 15 minutes and the conductivity of the phantom stents were in a location and orientation in the phantom that produced the worst case RF body coil MR scanner. The testing was performed according to ASTM F2182 and the Intera Philips Medical Systems, software version Release 10.6.2.0, 2006-03-10 whole Non-clinical testing of RF-induced heating was performed at 64 MHz in a 1.5 Tesla

electromagnetic fields in MRI yielded to the following maximal in vivo rises: based on these non-clinical tests and computer simulation of the patient exposure to the temperature rise. Fractured stents exhibited similar heating. Predicted in-vivo heating

- For landmarks above the umbilious, the calculated temperature rise was 3.2°C with an of 2.0 W/kg and a continuous scan time of 15 minutes. uncertainty upper bound temperature of 4.1°C for a whole body average SAR value
- For landmarks below the umbilious the calculated temperature rise was 3.2°C with an of 1.0 W/kg and a continuous scan time of 15 minutes. uncertainty upper bound temperature of 4.1°C for a whole body average SAR value

perfusion in the tissue outside the stent. include the cooling effects due to blood flood in the lumen of the stent and blood The actual in vivo rise is expected to be less than these values as the calculations did not

### Image Artifact Information

diameter and 6 mm beyond each end of the length of the stent when scanned in nonclinical testing using a Spin Echo sequence. With a Gradient Echo sequence the 2007-09-28 MR system with a transmit/receive head coil. each end of the length with both sequences partially shielding the lumen in a 3.0 Tesla image artifact extends 13 mm beyond the perimeter of the diameter and 12 mm beyond The image artifact extends approximately 7 mm from the perimeter of the device Intera (Achieva Upgrade), Philips Medical Solutions, software version Release 2.5.3.0

scanned safely with the MedicAlert Foundation (www.medicalert.org) or an equivalent It is recommended that patients register the conditions under which the implant can be

### ADVERSE EVENTS:

Potential complications associated with biliary stenting may include, but are not limited

Abscess

- Allergic reaction (to drug, contrast, device or other)
- Bile duct injury, perforation, tear, or dissection
- Bleeding
- Cholangitis
- Drug reaction
- Embolization including device, air, or tissues
- Entanglement of delivery system in deployed stent
- Hemobilia
- Hypotension/hypertension
- Liver abscess
- Need for urgent intervention or surgery
- Parenchymal hemorrhage Pancreatitis

- Recurrent stricture
- Page 31 of 38

- Sepsis/intection
- Sludge occlusion
- Stent fracture
- Stent migration
- Stent misplacement
- Tissue ischemia/necrosis
- Tissue/tumor ingrowth causing recurrent stenosis or obstruction

### HOW SUPPLIED:

Store in a cool, dry dark place

Do not use if package is opened or damaged

By" date shown on the label. Do not store catheters where they are directly exposed to organic solvents or ionizing radiation. Excessive aging may cause the polymers used in these products to deteriorate. Rotate inventory so that the catheters and other dated products are used prior to the "Use

#### Contents:

- One (1) Express LD Biliary Premounted Stent System
- One (1) Electronic DFU Reference Card

# OPERATIONAL INSTRUCTIONS:

### Recommended Materials:

- Micropuncture<sup>TM</sup> kit
- 0.035 in Guidewire of appropriate length
- Introducer sheath of appropriate size and length
- Syringe (10 cc or greater for prepping the premounted stent system)
- Inflation device (20 cc or greater) 3 Way Stopcock

# STENT PLACEMENT PROCEDURE:

### Patient Preparation

room equipped with appropriate imaging equipment. Patient preparation and sterile cholangiogram should be performed to map out the extent of the stricture in the biliary precautions should be the same as for any percutaneous cholangiogram procedure. A The percutaneous placement of the stent in the biliary tree should be done in a procedure

# Select Proper Premounted Stent System

- Premounted Stent System length (Refer to Table 1). Estimate the distance between the stricture and the entry site to select the proper
- and delivery balloon (Refer to Table 1). Measure the diameter of the reference duct to determine the appropriate diameter stent

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Note: To reduce the potential for damage to the duct, the inflated diameter of the Premounted Stent System should approximate the diameter of the duct just proximal and distal to the stricture.

3. Measure the length of the stricture to determine the length of the stent required. Size the stent length to extend slightly proximal and distal to the stricture. The appropriate stent length should be selected based on covering the entire stricture with a single stent (Refer to Table 1).

# Prepare the Premounted Stent System

- Do not use product after the "Use By" date indicated on the package.
- Open the box and remove the sterile package. Carefully inspect the sterile package before opening it. Do not use if the integrity of the sterile package has been compromised.
- Open package and remove hoop with Premounted Stent System.
- Remove the Premounted Stent System from the hoop.
- 5. Verify the stent is positioned between the proximal and distal balloon markers.

Caution: Do not attempt to manually reposition the premounted stent in any way. Check for bends, kinks and other damage. Do not use if any defects are noted.

- 6. Flush the Premounted Stent System guidewire lumen with normal saline.
- 7. Prepare inflation device/syrings with diluted contrast medium. The standard inflation medium is a 50/50 mixture of contrast medium and normal saline. Do not use air or any gaseous substance as a balloon inflation medium.
- Attach inflation device/syringe to stopcock; Attach to premounted stent system inflation port.

Note: A 10 cc syringe is recommended for use for aspirating this device.

- Open stopcock to Premounted Stent System. With the distal balloon tip pointing down
  and placed below the level of the inflation device/syringe, pull negative pressure for
  20-30 seconds. Carefully release to neutral for contrast fill.
- 10. Close stopcock to the Premounted Stent System; purge inflation device/syringe of all
- 11. Repeat steps 9 and 10 until all air is expelled. If bubbles persist, do not use the Premounted Stent System.
- 12. If a syringe was used for preparation, attach a prepared inflation device to stopcock

Note: A 20 cc Inflation device is recommended for use with this device

13. Open stopcock between the Premounted Stent System and the inflation device

### Delivery Procedure

 Insert the appropriate introducer sheath for the selected Premounted Stent System Reference Table 1 for the minimum acceptable size for this device.

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Caution: Always use an appropriately sized introducer sheath for the implant procedure to protect the puncture site. It is advisable to use an introducer sheath that is long enough to cross the stricture. Use of an introducer sheath minimizes the risk of dislodging the stent from the balloon during tracking.

- Advance a 0.035 in (0.89 mm) guidewire of appropriate length across target stricture.
   Pre-dilate the stricture as necessary with a balloon dilatation catheter using
- conventional techniques.

  4. After the stricture has been properly pre-dilated, remove the dilatation catheter.
- Backload the Premounted Stent System on to the proximal portion of the guidewire, while maintaining guidewire position across target stricture.
- Carefully advance the Premounted Stent System into the introducer sheath. Ensure introducer sheath stability before advancing the Premounted Stent System into the duct

Caution: If resistance is encountered to the Premounted Stent System prior to exiting the introducer sheath, do not force passage. Resistance may indicate a problem and may result in damage or dislodgement of the stent if forced. Maintain guidewire placement across the stricture and remove the Premounted Stent System with the introducer sheath

 Advance Premounted Stent System over the guidewire to target stricture under direct fluoroscopic visualization. as a single unit

Caution: If strong resistance is met during advancement of the Premounted Stent System, discontinue movement and determine the cause of the resistance before proceeding. If the cause of resistance cannot be determined, withdraw both the Premounted Stent System and introducer sheath as a single unit.

8. Utilize the proximal and distal radiopaque balloon markers as well as the radiopaque stent as reference points to position the stent in the stricture. During positioning, verify that the stent is still centered within the marker bands and has not been dislodged. Do not deploy the stent unless it is properly centered on the balloon and properly positioned within the target stricture. If the position of the stent within the stricture is not optimal, it should be carefully repositioned or removed.

Removal of a stent that has not been expanded: Do not attempt to pull a Premounted

Removal of a stent that has not been expanded: Do not attempt to pull a Premounted Stent System that has not been expanded back into the introducer sheath, as dislodgement of the stent from the balloon may occur.

The Premounted Stent System should be withdrawn until the proximal end of the stent is aligned with the distal tip of the introducer sheath. The introducer sheath and Premounted Stent System should be removed as one unit.

### Deployment Procedure

 To deploy the stent, slowly inflate the Premounted Stent System to at least the opening pressure shown in Table 1 using an inflation device. Higher pressure may be necessary to optimize apposition against the stricture. Balloon pressures must not exceed rated burst pressure 12 atm (1216 kPa).

Note: It is strongly recommended that the guidewire remain across the stricture until the procedure is complete.

2. After deploying the stent, deflate the balloon by pulling negative pressure on inflation device until balloon is fully deflated.

Caution: Allow adequate time for the balloon to fully deflate prior to removal. Observe fluoroscopically that the balloon is fully deflated.

3. Maintaining proper introducer sheath support, very slowly withdraw the balloon. Observe under fluoroscopy to ensure that the balloon disengages from the stent.

Caution: If resistance is encountered upon attempted removal, do not force removal, use fluoroscopy and conventional techniques to determine and remedy the cause of resistance before proceeding.

4. Confirm stent position and deployment using fluoroscopic techniques. For optimal results, the entire stricture should be covered by the stent. Fluoroscopic visualization should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal reference duct diameter.

5. If re-sizing is necessary, re-advance the SDS, or another balloon catheter of appropriate size, to the stented area using conventional techniques.

6. While observing under fluoroscopy, inflate the balloon to the desired pressure; do not exceed the rated burst pressure. Do not expand the stent beyond maximum stent diameter as shown in Table 1. Deflate the balloon and follow the instructions as outlined in step 3 above.

7. Reconfirm stent position and fluoroscopic result. Repeat inflations until the desired result is achieved.

While maintaining negative pressure in the balloon, remove the SDS from the body and through the introducer sheath.

Table 2. Typical Express® LD Biliary Premounted Stent System Compliance

Pressure	Balloo	Balloon Diameter (mm)	ter (mm	)		
(atm-kpa)						
	5.0	6.0	7.0	8.0	9.0	10.0
	mm	mm	mm	mm	mm	mm
6 - 608	N/A	5.79	6.69	7.60	8.67	9.57
7 - 709	4.66	5.83	6.76	7.70	8.75	9.69
8.0 - 811*	4.72*	5.89*	6.85*	7.83*	8.87*	9.80
9.0 - 912	4.77	5.97	6.93	7.92	8.93	9.88
10.0 - 1013	4.83	6.02	6.99	7.99	9.00	9.97*
11 - 1115	4.88	6.08	7.04	8.05	9.05	10.03
12 - 1216**	4.92	6.11	7.08	8.10	9.10	10.08
*Nominal Pressure	sure					
**Rated Burst Pressure. DO NOT EXCEED	Pressure	DO NO	T EXCE	ED.		
User should confirm stent diameter angiographically during	nfirm ste	ent diame	eter angi	ographica	ılly durin	8
balloon inflation	)n.					

#### WARRANTY:

design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by instruments. to merchantability or fitness for a particular purpose, with respect to such resterilized and makes no warranties, express or implied, including but not limited BSC assumes no liability with respect to instruments reused, reprocessed or for it, any other or additional liability or responsibility in connection with this instrument use of this instrument. BSC neither assumes, nor authorizes any other person to assume incidental or consequential loss, damage or expense directly or indirectly arising from the instrument and the results obtained from its use. BSC's obligation under this warranty is treatment, surgical procedures and other matters beyond BSC's control directly affect the sterilization of this instrument as well as other factors relating to the patient, diagnosis, of merchantability or fitness for a particular purpose. Handling, storage, cleaning and operation of law or otherwise, including, but not limited to, any implied warranties Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the limited to the repair or replacement of this instrument and BSC shall not be liable for any

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